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Assessment of the Behavioral and Physiologic Responses of Anxious Pedodontic Patients to Nitrous Oxide-Oxygen: A Double-Blind Study

John Edward Nathan

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ASSESSMENT OF THE BEHAVIORAL AND PHYSIOLOGIC
RESPONSES OF ANXIOUS PEDODONTIC PATIENTS TO
NITROUS OXIDE-OXYGEN: A DOUBLE-BLIND STUDY

John Edward Nathan
B.S., D.D.S.

A Dissertation

Submitted in Partial Fulfillment of the
Requirements for the Degree of
Master of Dental Science

at

The University of Connecticut

1983

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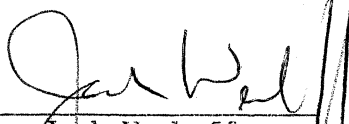
Master of Dental Science Thesis

ASSESSMENT OF THE BEHAVIORAL AND PHYSIOLOGIC
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TO NITROUS OXIDE-OXYGEN: A DOUBLE-BLIND STUDY

Presented by

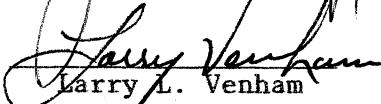
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A. INTRODUCTION

1. Objective

A number of studies have documented the safety, ease of administration, and analgesic effectiveness of nitrous oxide. This agent has acquired widespread use as a tool for managing young dental patients. Clinical experience has suggested that nitrous oxide analgesia reduces the anxiety and uncooperative behavior children commonly manifest during dental treatment. To date, there has been no controlled empirical investigation of the impact of nitrous administration on children's dental attitudes and behavior; the belief in its usefulness in modifying anxiety is based solely on clinical impression and professional endorsement.

This project was designed to empirically examine these clinical impressions. The project entailed an evaluation of the effectiveness of nitrous oxide in reducing children's dental anxiety and its behavioral manifestations. Children receiving nitrous oxide-oxygen were compared with children in appropriate control conditions, using a combination of self-report, behavioral, and physiological measures. Since dental treatment involves repeated visits, a longitudinal approach was used to study the child's developing response to a series of dental experiences. With this design, it was possible to assess not only the short-term effect of nitrous oxide on children's response to a specific dental treatment visit, but also its impact on the emergence of coping skills across several visits. The need for continued administration of nitrous oxide was also examined.

2. Background

Dental Anxiety in Children: Its Incidence, Etiology, and Implications

The recent pedodontic literature reflects a growing concern with the problem of dental anxiety, although its prevalence, acquisition, and long-term ramifications are still largely unknown. Nonetheless, it is widely acknowledged that young children commonly respond to the stress of dental treatment with fear and anxiety. Since the dental situation is openly viewed as unpleasant in our society and does involve a degree of discomfort, it is understandable that a dental visit can represent a particularly threatening event for a young child. Hawley et al.¹ studied children from low socioeconomic status families during their first dental visit, and observed a high incidence of anxious, uncooperative behavior. Fearful and disruptive responses were most common among the younger children and diminished in frequency as the child's age at the first visit increased. The observed percentage of children reacting negatively was 53% among 2 year olds, 33% among 3 and 4 year olds and 13% among 5 to 7 year olds. Simpson et al.² measured physiological stress responses of 3 and 4 year olds undergoing their first dental experience. Elaborate precautions ensured that the children were initially unaware of the nature of the visit. Physiological arousal indicative of anxiety was produced not only by the dental examination procedures, but also by exposure to the dental environment per se (e.g., sight of stranger in a white coat, identification of stranger as a dentist). A few studies of sequential dental visits have appeared; these studies document that dental anxiety is not a transient phenomenon

only manifested during initial visits. Koenigsberg and Johnson³ observed 61 children, ranging in age from 3 to 7 years, during their first three dental visits. At each visit, children were given a rating describing how positively or negatively they responded to treatment. The majority of children were found to receive the same rating on successive visits, suggesting that the child's resistance to treatment tends to be a relatively stable individual characteristic.

Howitt and Stricker⁴ compared the physiological response of dentally experienced school age children during a dental examination visit, a series of dental treatment visits, and a six month recall examination visit. The authors reported that the youngsters' arousal levels were reduced as they gained experience in the dental situation. Howitt and Stricker did not separately analyze the several treatment visits and therefore could not document possible changing responses across the course of the treatment series.

Venham et al.⁵ and Venham and Quatrocelli⁶ used behavioral, self-report and physiological measures to assess the responses of 2-5 year old preschoolers during their initial series of dental visits. The series of six visits included an initial examination visit, four treatment visits, and a final polish and prophylaxis visit. Significant differences were found over the six visits in anxiety, cooperative behavior, and heart rate. During the first three treatment visits, the young patients' response became increasingly negative. Their response then became increasingly positive over the final treatment visit and polish visit. The improvement seen

during the last two visits suggested that the children were able to use their accumulating experience to perceive the dental stress more accurately and to develop coping skills. Although dental anxiety was lower overall in the final treatment visit, the negative response to local anesthetic injection remained unchanged; this observation suggested that experience enabled the children to identify a specific stressful procedure. These longitudinal studies suggest that dental anxiety is an ongoing phenomenon, which evolves in a complex and variable manner as dental experience accumulates.

Sermet⁷ and Furniss⁸ have described the extensive variability among children in their behavioral manifestations of dental anxiety. Typically, anxiety is expressed through a variety of uncooperative maneuvers. A proportion of children refuse either to enter the operatory or to open their mouths. Some children actively resist by struggling, screaming and crying; others behave less overtly anxious, but remain tense and passively cooperative. Some youngsters employ delaying tactics to postpone treatment. Still others develop behavioral symptoms outside the dental environment (e.g., experience night terrors).

The variability in children's dental anxiety has been described by Swallow⁹ as a continuum. At one extreme of this continuum are those children who readily accept any type of dental treatment; at the other are those who resist every form of treatment offered. The majority of children manifest varying intermediate degrees of anxiety.

Sermet⁷ and Shaw¹⁰ have reviewed theoretical issues related to the etiology of dental anxiety. Existing theories are largely speculative, representing untested extrapolations of psychoanalytic, personality, or S-R learning theory. Psychoanalytically oriented workers have stressed the special significance the oral zone may have for some individuals. An orally fixated person may perceive dental procedures as a form of attack.¹¹ Some authors, noting the large variability among children in anxiety manifestations have emphasized the role of basic personality factors such as trait anxiety, neuroticism, extraversion, or dependency.^{7,12} Other workers^{13,14} have contended that dental fears are largely acquired, i.e., responses conditioned by familial attitudes and/or previous unpleasant experience. A conceptual model which combines both dispositional and specific experiential variables has not yet been presented.

Several retrospective studies of dentally anxious adults have been conducted using interview and questionnaire approaches.¹²⁻¹⁶ These studies suggested traumatic dental experience during childhood as one primary factor in the acquisition of negative dental attitudes. Reports of unfavorable attitudes toward dentistry among family members were also found more frequently in fearful than nonfearful adults. The importance of painful experience and early negative family attitudes has supported the usefulness of viewing dental fears as learned responses to the stimuli intrinsic to the dental context. However, these findings do not preclude the potential importance of personality traits in modulating the learning process. For example,

Forgione and Clark¹⁷, reanalyzing Shoben and Borland's data,¹³ reported that low pain tolerance and high trait anxiety were further important contributors to odontophobia.

Sermet⁷ and Shaw¹⁰ studied 100 dentally anxious and 100 dentally non-anxious children. Emotional attributes and medical and dental histories of both child and parents were assessed. Dental anxiety emerged as a complex phenomenon which reflects multiple interacting variables. Significant differences between the two groups of children were found in their introduction to dentistry, their dental and medical experiences, their emotional disorders and their mothers' dental attitudes and experiences.

Although much remains to be learned about the origins of dental anxiety, certain general conclusions seem justified. Most children do experience anxiety in their initial dental contacts, but wide individual differences are apparent in the extent of this anxiety and its behavioral manifestations. A multitude of factors, reflecting both personal and familial attitudes, history, and dispositional variables, appear to contribute to determining initial level of anxiety. The course and content of dental experience then exerts a significant influence on the child's anxiety. This experience has the potential to either exacerbate or ameliorate dental fears. Research to date has served to identify a number of relevant variables contributing to a dentally anxious reaction. However, the nature of the interaction among these attitudinal, dispositional, and experiential variables in producing dental anxiety remains essentially unexplored.

Dental anxiety has many important ramifications. Children's anxious reactions are widely acknowledged as a major source of frustration and urgency in the current field of pedodontics.^{18,19} Uncooperative children demand considerable dedication and expertise in child management techniques from the dental staff. Time-consuming behavioral management procedures may be required to render treatment, and both efficiency and quality of service typically suffer. The child typically expresses his/her anxiety through resistive or combative behaviors which themselves contribute to generating an extremely unpleasant and potentially traumatic experience for the child. Such behavior may elicit control techniques which damage the child's self-esteem and impede the acquisition of coping skills.^{20,21} Thus, a self-reinforcing circularity often develops which maintains or even increases the child's anxiety.

A number of workers have suggested that dentally anxious children resist proper oral hygiene and other preventive action.^{7,22} Fear of the dental situation is postulated as a major factor in avoidance of needed dental treatment.^{14,23,24} It is therefore apparent that a major objective of the pediatric dentist must be to help children develop a positive attitude toward dental care and to thus encourage optimum dental health throughout life.

Techniques currently advocated for the management of patient anxiety will be discussed below. As background for this discussion a critical review of the nature of anxiety and approaches to measuring children's anxiety in the dental setting is needed.

The Measurement of Children's Anxiety During Dental Visits

There has been considerable theoretical and empirical work directed toward the definition and measurement of anxiety. Early simplistic notions have gradually been replaced with the recognition that anxiety is a multidimensional phenomenon involving complex cognitive, emotional, and motivational processes.

Major theorists concur that anxiety is an organismic state of undirected arousal induced by the perception of threat.²⁵⁻²⁸ The construct refers to an unpleasant emotional state characterized by feelings of tension and apprehension and by alterations in central and autonomic nervous system activity. This arousal state mobilizes the organism's energy for non-specific action; the autonomic arousal pattern is appropriate to support either "fight" or "flight" behavior.

Stimulus or situational variables play a prominent role in discriminating anxiety from other emotional states. Anxiety is defined as the non-specific response to a situation which is both threatening and ambiguous. As emerging information clarifies the situation, anxiety is replaced by specific emotions such as instrumental fear or anger.

Cognitive variables also play a critical role in defining the emotional state. The primary cognitive appraisal of threat is an internal subjective process which forms the initial step in anxiety arousal. A continuing process of appraisal and reappraisal contributes to information collection and ongoing evaluation of the situation. During the anxiety phase, adequate information is not available to clearly define the dimensions and characteristics of

the stressful situation, and appropriate direct action cannot be identified. When the nature of the threat and the appropriate coping response is determined, the non-specific arousal is channeled into direct action and anxiety is alleviated.²⁹

Anxiety also has important motivational components. Since anxiety is an aversive state, there is a strong motive to resolve uncertainty and to choose a course of action. When anxiety is mild, it promotes a constructive vigilance. When severe, it can serve maladaptively to focus the individual's attention onto a few situational cues and propel the individual into premature action. Thus, the individual may accept a hypothesis based on minimal data and act correspondingly. Defense mechanisms may become prominent, and the hypothesis becomes inflexible in the light of emerging contradictory information.

Young children have limited cognitive skills, a restricted range of coping abilities and limited experience coping with stress; they could therefore be expected to be especially prone to the latter type of maladaptive response in anxiety provoking situations. The child who responds angrily and combatively to a dental exam, the child who enters the operatory loudly crying and protesting, the child who remains silent and passively resistant -- each can be viewed as perceiving the dental situation as highly threatening and anxiety-provoking; and each child has responded with a rapid and persistent activation of defense mechanisms compatible with his/her response style.²⁹

The measurement of anxiety is a complex field. Not suprising in light of the multidimensional nature of anxiety is the plethora of approaches developed for its quantification. Basic approaches have included self-report instruments, behavioral observation, and physiological techniques.

As will be seen below, each of these three approaches is subject to certain objections and restrictions. The ultimate problem resides in the recognition that anxiety per se is an unobservable internal state which differs markedly among individuals in its subjective and objective manifestations.³⁰ Correlational studies have typically reported low correlations among independent indicators of stress, even when all the measures are in a single domain, such as physiological arousal.³¹ An intraindividual methodology improves these correlations.³² It is likely that this response discrepancy reflects, at least in part, individual differences in coping processes and styles. Thus, while one individual may experience anxiety as a directly felt cognitive and emotional process, another may predominately experience somatic manifestations, while a third may have minimal affective and autonomic arousal and rapidly discharge energy into direct action. Individual response patterns may similarly be prominent within each domain - affective, physiological, and behavioral. Subjects differ markedly in their relative use of different behaviors when anxiety is present. Characteristic patterns of autonomic reactivity are also apparent: some individuals tend to show lability in cardiovascular indices under emotional stress; other individuals typically manifest gastro-

intestinal mobility; yet other subjects characteristically show lability in electrodermal phenomena. These considerations necessitate the conclusion that no one single index of anxiety can serve as an ultimate measure, equally valid for all subjects. As no ultimate anxiety index is available, each indicator must have firmly demonstrated construct validity, such that the measure enters into a network of relationships with other variables according to theoretical expectations. Since anxiety is a multidimensional phenomenon with variable specific manifestations, multiple indicators are needed which span the intrapsychic, behavioral, and physiological realms. Finally, measurement paradigms must provide for within-subjects analyses of patterning to account for varying individual response styles.

The self-report approaches have assumed an important and well-founded position in anxiety research. The value of this technique lies in its ability to provide data which is inaccessible to more objective observational approaches. Since anxiety is an internal state based on unobservable cognitive processes, the individual's self-report of these internal processes can provide valuable information. Previous research has clearly demonstrated the value of self-report measures of anxiety.^{32,33}

Several self-report measures have been developed for the specific assessment of dental anxiety; these measures include the Corah Dental Anxiety Scale,³⁴ The Melamed Scale of Dental Anxiety,³⁵ and the Kleinknecht Dental Fear Scale.¹⁴ These scales require the subject to verbally rate his/her nervousness when exposed to a number

of hypothetical dental situations and stimuli. The existing scales are therefore appropriate only for dentally experienced subjects who are sophisticated enough to manipulate an ordinal scale.

The major drawback of the self-reports is that they represent a self-description offered by a highly ego-involved observer. Self-reports can be readily distorted to comply with perceived expectations or social desirability. Therefore, the validity of such measures must rely heavily on the subject's skills at self-observation and his/her willingness to respond objectively and honestly.

The latter requirements seriously restrict the utility of self-report anxiety measures with young children. Such subjects typically have limited ability to observe their internal processes and to label their affective experiences. Communication skills are poorly developed and young children often become reticent with unfamiliar adults. Furthermore, preschool children would be particularly likely to utilize primitive ego defensive mechanisms, such as the denial of anxiety.

Several approaches have been developed in an attempt to circumvent these difficulties in measuring young children's anxiety. These approaches rely on projective techniques which permit the child to respond non-verbally and on a more directly experiential level. Projective techniques minimize the tendency to deny ego-threatening material and also reduce the distortion produced by the subject's attempt to provide socially desirable responses.

The Human Figure Drawing task³⁶ (Goodenough, 1926) is a time-honored tool for clinical child assessment. Studies of human

figure drawings by children in stressful situations have yielded a number of factors believed to reflect anxiety.³⁷⁻³⁹

Handler and Reyher⁴⁰ have reviewed fifty-one studies of the HFD task. Features such as omission, distortion, size increase or decrease, head or trunk simplification, pressure increase, and detail loss reliably emerged as anxiety indices. Such findings have provided a basis for quantifying the HFD as an anxiety measure.⁴¹ Scores on the HFD task exhibit low but significant correlations with other measures of anxiety.⁴⁰⁻⁴²

Children undergoing dental treatment were administered the HFD task by Eichenbaum and Dunn⁴³ and by Baldwin.⁴⁴ These authors did not evaluate the drawings quantitatively, nor did they statistically assess changes in the drawings under differing treatment conditions. Sonnenberg and Venham⁴⁵ used the HFD task to obtain a quantitative anxiety score in young children undergoing a series of dental visits. Additional measures included clinical ratings of the child's anxiety and cooperative behavior, heart rate, basal skin response, and Venham Picture Test⁴⁶ (see below). The HFD score was significantly related to 4 of the 5 other anxiety measures. These findings suggest the potential utility of the figure drawing task as a measure of children's anxiety in the dental context.

The Venham Picture Test⁴⁶ is a picture selection task designed to measure children's dental anxiety. A stylized cartoon figure is portrayed in varying states of fear, crying, sadness, and happiness; the child is asked to choose the figure "who feels most like you do right now" from successive standard paired presentations. Venham

administered the Picture Test and several other anxiety measures to preschool children experiencing sequential dental visits. The Picture Test scores correlated significantly with the other anxiety measures, which included the Human Figure Drawing, clinical ratings of anxiety and cooperative behavior, heart rate, and basal skin response. Klorman et al.⁴⁷ studied 60 pedodontic patients, ranging in age from 5 to 12 years, undergoing restorative treatment. The patients were administered the Venham Picture Test and the Melamed Scale of Dental Anxiety.³⁵ The latter scale requires the child to rate on a 5-point scale his/her nervousness in 8 hypothetical dental situations. Additionally, immediately prior to the dental treatment each patient's mother was asked to rate her child's nervousness. Maternal ratings of the child's situational anxiety and the child's self-reported fear of dentistry yielded significant prediction of the Picture Test Score (multiple $R = .56$). Klorman et al.⁴⁷ also reported observations of 105 pedodontic patients, ranging in age from 3 to 14, undergoing a variety of dental experiences. The Venham Picture Test and the Melamed Scale of Dental Anxiety were administered prior to the visit; the child's cooperation during the visit was rated on a 4-point scale by the practitioner. Picture Test scores yielded significant correlations in the predicted direction with both the child's self-reported dental anxiety and the practitioner's cooperativeness ratings. In summary, findings from two laboratories tend to support the validity of the Venham Picture Test in measuring children's situational anxiety.

Behavioral observation is a second major approach to the quantification of anxiety. With behavioral observation, the measurement tasks become more remote from the intrapsychic experience which constitutes anxiety; therefore, careful research validation is needed to establish the behavioral signs of anxiety in the target population. However, behavioral techniques have an important advantage over self-report measures in that the basic data are less easily distorted by social expectations; the lesser controllability of behavioral responses will be particularly true of young children. Nonetheless, the danger still remains that behavioral signs of anxiety may be inhibited by some subjects. An additional problem resides in the marked differences among individuals in the propensity to display given types of anxious behaviors.

Behavioral rating scales have been the most commonly used indices of anxiety in dental research. An example is the widely used Frankl Scale⁴⁸ in which the child's response to dental treatment is rated on a 4-point scale ranging from definitely negative to definitely positive. The advantages of rating scales include ease of administration and conceptualization (Lytton, 1973). The rater uses the trait as an organizing concept which allows him/her to select relevant cues and to superimpose a dimension on the subject's behavior, thus the overall impression afforded by the rating may bring out a quality or unity to the behavior that a mere count of discrete behaviors may be unable to reveal. In assigning ratings, the rater is able to take account of individual response styles in behavior and to consider infrequent but significant behaviors. Thus, the rating represents a

high degree of abstraction from the basic observational data. The major drawback of the rating procedure lies in the possible undetected bias and distortion of data. The scorer weighs the evidence on which the rating is based in a complex manner which is not easily specified or standardized. The ego-involvement of the rater may further contribute to bias. When successive ratings are assigned to a given subject, the scores are likely to be non-independent (the "halo effect"). Finally, traditional rating scales which use a limited number of scale points impose major restrictions on statistical analysis techniques. Flexibility in statistically analyzing such ratings can, however, be increased by using visual analogue scales, such as those described by Aitken.⁴⁹ These scales require the rater to score the trait along a linear scale for which only the end points are designated and defined. The score is then obtained by measuring the distance from the lower end point to the point marked by the scorer. Such scores yield a normal distribution and, like other continuous variables, can be analyzed using parametric techniques. This adaptation is particularly valuable when multivariable analytic techniques are to be used.

In light of the significant drawbacks of rating procedures, their inclusion may have its chief utility in cross-validating more objective behavioral observation techniques and in ensuring that important behavioral dimensions are not "missed" by the summary of discrete behavioral events.

Because of their ease of administration, ratings may also provide a useful means of obtaining parental reports. Parental ratings of the

child's situational distress have been used in a number of dental studies and appear to be predictive of the child's response to dental treatment. Such measures suffer from similar deficiencies of reporting bias and inaccuracy as do self-ratings; furthermore, these problems may be magnified by using a secondary source of information. Nonetheless, a parent may be more sensitive to the manifestations of anxiety in his/her particular child than an unfamiliar observer, and more able to express and quantify this anxiety than the cognitively and verbally limited child. Therefore, the inclusion of parental reports in the research design seems a reasonable precaution for cross-validation purposes.

Objective behavioral scoring instruments are based on the premise that some type of quantitative behavioral summary or "count" will provide a valid and meaningful measure of response tendency. Typically, such an instrument is based on the frequency of occurrence of a number of discrete, objectively-defined and mutually-exclusive behaviors. Construction of the instrument, in theory, presupposes an ability to specify particular behaviors which uniquely reflect anxiety. In reality, it is seldom possible to infer a unique emotional state from behavioral observation alone; a given behavior such as refusal to open the mouth may, for example, reflect anger or anxiety. Definition of the specific emotional state must rely not only on the behavior, but also on contextual cues and validation by independent measures, such as self-report or physiological data.

Since children differ in their behavioral response pattern under emotional distress, the instrument must be sufficiently inclusive to

represent these divergent behavior patterns. The quantification system must also take into account that gradations in anxiety may be reflected in the intensity or persistence of a particular behavior rather than in the variety or overall frequency of "anxious behaviors" exhibited. Few attempts to objectively observe and quantify the child's behavior in the dental setting have emerged to date. Therefore, the development of an objective behavioral measurement instrument is a major prerequisite to the refinement of behavioral research in the pedodontic field.

Kohlenberg et al.⁵¹ described a precise and objective behavioral measurement technique, quantifying two behavioral end points. This instrument was appropriate to their research goal, which was the evaluation of a behavior modification program focusing on specific target behaviors. However, such a measurement technique is clearly too restricted for general research use, since it does not adequately represent the range of anxious behaviors likely to be exhibited by young children.

White et al.⁵¹ developed a check list of discrete approach and avoidance behaviors which might be exhibited in the dental setting. However, the behavioral quantification was essentially a complex rating procedure in which the presence and intensity of certain behaviors over the course of the treatment session were scored on 2-point or 4-point scales.

Melamed et al.³⁵ developed a 27-item behavioral profile for use in evaluating dental management techniques. Each behavioral category, representing a discrete molecular behavioral unit, was weighted by a

factor based on dentists' ratings; this factor represented perceived disruptiveness of the particular behavior to the treatment process. This approach was suitable for research evaluating child behavior purely from a management perspective since the primary interest was the impact of anxiety on treatment efficiency. However, this approach is less appropriate for research where the major focus is the child's dental anxiety per se, its evaluation and alleviation.

Sawtell et al.²² operationally defined six behavior response classes whose frequency could be tabulated during a dental visit. One behavioral response class could occur only during entry to the operatory, while a second behavior class referred to dental staff behavior. Since children differ markedly in their overt response to dental treatment, specification of a wider range of response classes seems important to ensure tapping the total range of anxious behavior.

Chambers et al.⁵² and Fields et al.⁵³ described a method for assessing the amount of disruptive behavior children 30-60 months of age display during dental treatment. Modifying their North Carolina Behavior Rating Scale, which consisted of eight discreet behaviors in its original form, to four behavior categories, (high-hand, leg movement, crying protest, and oral-physical resistance) the authors report this scale to be a valid and reliable tool for research involving child behavior in the dental setting. This scale, reflecting behavioral endpoints, similar to the scale developed by Venham et al.⁴⁶ attempts to accurately represent the intensity, frequency, and duration of the full range of behaviors seen by pedodontic patients.

In summary, there have been several attempts to quantify child behavior in the dental setting; these studies have helped to identify some appropriate behavioral end points which reflect the child's dentally-related anxiety. However, further work is needed to develop behavioral categories which adequately represent the full range of behaviors exhibited by dentally anxious preschool children. A quantification system which summarized these multiple behavioral categories and accurately represents their intensity and duration is also needed.

The final major approach to the measurement of anxiety is the physiological recording. Several heavily debated issues related to the physiological measurement of emotion will be discussed.

One controversy concerns the extent to which emotional arousal represents a unidimensional versus a multidimensional phenomenon -- that is, the question whether all emotions share a common global physiological activation or whether each specific emotional state is characterized by a unique activation pattern. Another issue concerns the extent to which patterns of physiological arousal are determined by situational cues. A final issue relates to the presence of reliable individual patterns of physiological arousal across diverse situations.

Early research conceptualized emotional arousal as a unidimensional phenomenon characterized by diffuse sympathetic activation including heart rate and blood pressure elevations, peripheral vasoconstriction, a decrease in gastrointestinal motility, and cortical alpha blocking.⁵⁴⁻⁵⁷

Lindsley⁵⁸ hypothesized that input from the sensory systems was projected, via lower brainstem areas, onto non-specific cortical regions. This process yielded a continuum of cortical arousal. The aroused brain, according to Lindsley, directed its activity peripherally through sympathetic discharge. This conceptualization led to the measurement of emotional arousal in terms of unpatterned intensity gradients of physiological activation.

This unidimensional concept of arousal has been challenged. Duffy⁵⁹ and Lang et al.⁶⁰ have argued that emotions have multidimensional aspects. Not only intensity but directionality (e.g., approach-withdrawal or pleasantness-unpleasantness) are involved, implying the presence of patterns of activation rather than a simple linear activation gradient. Considerable research has documented that physiological systems do not respond in a uniform global fashion; these findings support the concept of response patterning in emotional states.^{59,61,63} Homeostatic mechanisms, which continually regulate physiological activity, produce response patterns. For example, complex reciprocal interactions between autonomic and cortical activity have been demonstrated.^{57,64,65} These findings emphasize the importance of evaluating not only relationships within a single physiological system but also differential relationships (e.g., reciprocal increases and decreases) across several systems during emotional arousal.

Patterning of physiological responses is also evident in the differing response latencies across various systems. These differing latencies are not taken into account when, as is traditionally done,

activity is measured at set intervals following a stimulus rather than at peak levels. Future research can help to elucidate response patterning by evaluating each response system in terms of its respective latency to peak amplitude.

Considerable research has addressed the issue of stimulus-response specificity in emotional states. The concepts of S-R specificity argues for a prominent role of situational cues in determining physiological arousal patterns. The cognitive process theory of anxiety^{26,27} is widely accepted; this theory attributes major importance to perceptual and cognitive factors in defining anxiety. Thus, the subjective experience of anxiety is heavily influenced by situational cues as well as by changes in physiological activity.^{27,63,66} Schacter and Singer⁶⁷ reported a series of experiments which clearly demonstrated the role of contextual cues in programming the subjective interpretation assigned to a physiological arousal pattern. Subjects were administered epinephrine, a drug which stimulates the sympathetic nervous system, during exposure to varying social-environmental conditions. The authors concluded that "the same state of physiological arousal could be labeled 'joy' or 'fury' or 'jealousy' depending on the cognitive aspects of the situation."⁶⁷

Averill and Opton⁶³ were unable to replicate this effect with administration of norepinephrine, a potent sympathetomimetic drug. The differential effect of epinephrine and norepinephrine on affective experience probably is attributable to differences in their CNS action rather than their peripheral effects.

While Schacter and Singer's findings strongly support the role of situational factors in defining emotional states, it is nevertheless also likely that different emotions are characterized by varying physiological response patterns. Ax,⁶⁸ Funkenstein,⁶⁹ and Schachter⁷⁰ have demonstrated that different physiological manifestations are observed in fearful and angry states. Correlated with a fearful state were increases in heart rate, palmar conductance, forehead temperature, and diastolic blood pressure. With anger, the responses were less clear-cut but changes in systolic and diastolic blood pressure were characteristic.³¹ Physiological responses seen during fear were similar to the effects produced by epinephrine administration. These results led Funkenstein to suggest that fear exhibited largely an epinephrine-like response, while anger seemed characterized by a mixture of norepinephrine and epinephrine-like responses.

Although significantly different physiological response patterns are seen during differing emotional states, correlations among specific physiological measures of emotion typically are low.³¹ Similarly, low correlations have been observed between physiological and self-report indices of emotion.^{30,31} Such discrepancies among measures may be partially explained by the concept of individual response specificity.^{60,61,71,72-74} This concept argues for the existence of varying stereotypical physiological response patterns to stress across different individuals. It has often been observed that subjects respond to a multitude of threatening stimuli (e.g., shock, cold pressor, verbal stress) in the same characteristic patterns over

repeated trials. For instance, some subjects respond primarily in cardiovascular measures and show less lability in other modalities. Other subjects respond with equal intensity across several response systems. Still others show little lability in any physiological end point. Differences have also been observed between "rigid reactors" and "random reactors"; the former react in a consistent pattern to every stimulus situation, while the latter react with varying predictability.⁶⁰

Situational specificity probably also accounts for some of the variability seen in physiological responses. Different stimuli or demand situations can evoke different patterns of activation with both sympathetic and parasympathetic components.⁷⁴ It is likely that both situational and individual response specificity co-occur and interact to produce the observed physiological pattern.⁷⁵ Analyses of covariance have been shown to be useful in partialling out of these two specificity effects.⁷⁶

Additionally, Katkin⁷⁷ has argued that the use of mild stressors will improve the correlation between self-report and physiological measures. Mild stressors appear maximally effective in eliciting autonomic responses which correspond to subjects' self-reported anxiety levels.

Considerable progress has been made toward the development of specific physiological measures of anxiety. The orienting reflex shows promise as an index of anxiety.

Pavlov⁷⁸ first described the OR as a "What is it?" response, in which the organism briefly attends to a novel stimulus. Berlyne⁷⁹

characterized it physiologically by an increase in muscle tone and skin conductance, a biphasic cardiac response (heart rate increase followed by decrease), peripheral vasoconstriction, and decrease in skin temperature. Gross movements related to attending also occur. The OR can be contrasted with the defensive reflex (DR) or startle reflex. The DR was described by Sokolov⁸⁹ as being more rapid than the OR and typically evoked by a stronger stimulus. A monophasic cardiac increase characterized the DR.⁸¹

Habituation, a progressive decrease in response magnitude with successive identical stimuli applied at discrete intervals, is a biological phenomenon observed at all phylogenetic levels. Since the novelty of a stimulus declines with repeated presentations, it is not surprising that the OR to a novel stimulus habituates across trials. However, the DR elicited by intense stimulation does not habituate. This process of habituation contributes to elucidating the adaptive functions of these two reflexes. The organism can most effectively deploy its attention to salient environmental features if the attentive response to a purely novel stimulus declines as the stimulus becomes less novel. However, it seems adaptive to continue responding to an intense and therefore potentially noxious stimulus. Graham and Clifton⁸¹ have identified the OR as a process of "stimulus intake" with increased responsiveness and the DR as "stimulus rejection" with increased perceptual vigilance.

Since anxious subjects would be expected to perceive neutral stimuli as more threatening than non-anxious subjects, one might predict that anxious subjects would exhibit greater perceptual

vigilance and delayed habituation to such stimuli. There is substantial evidence that anxious subjects and subjects under laboratory stress have slower rates of OR habituation than control subjects. Davis, Malmo, and Shagass⁸³ reported impaired habituation of the electromyogram in anxious patients. Delayed habituation of the skin conductance response has also been observed in anxious patients⁸² and in normal subjects exposed to threat.^{84,86} Therefore, rate of OR habituation has potential as a physiological index of anxiety level.

Another physiological measure believed useful in differentiating anxiety from other emotional states is the spontaneous skin conductance response. The spontaneous or non-specific skin conductance response (SCR) is a transient electrodermal change which occurs during a baseline period without discrete stimulation. The frequency of the SCR (the number of SCRs in a unit time) is the standard index of this spontaneous activity. Katkin^{77,87} and Kilpatrick⁸⁸ reported that this index of electrodermal lability is sensitive to laboratory stress and anxiety. Szpiller and Epstein⁸⁶ reported comparable results. Subjects in one experimental group were instructed to execute a motor response to avoid shock; subjects in a second group executed a motor response which was not instrumental in avoiding shock. Subjects in the latter group were presumably more anxious, since they were exposed to a threat in the absence of an appropriate coping response. Significantly more SCRs were produced by subjects in the non-instrumental than in the instrumental group.

Lader and Wing⁸² observed a higher frequency of spontaneous SCRs in chronically anxious patients than in normal controls; a drop in the

SCR frequency was seen when relaxant medication was administered to the anxious patients. Pooling all subjects, a high correlation was found between SCR frequency and habituation rate of elicited conductance responses. This correlation provides support that these two physiological measures are tapping a common dimension of anxiety.

Reliable correlations have not typically been found between spontaneous skin conductance activity and activity in other physiological systems. However, Hart⁸⁹ reported that anxious subjects exposed to 100 db acoustic stimuli typically showed a pattern of skin conductance responses and heart rate accelerations suggestive of a DR; whereas normal controls typically showed biphasic heart rate responses resembling an OR. Skin conductance responses were elicited less frequently in the normal than the anxious subjects.

The findings reviewed above have led several investigations to hypothesize that anxiety is characterized by a state of heightened perceptual vigilance with continual appraisal of incoming stimuli.^{77,82,86,90} Self-propagating mechanisms of CNS activity have been postulated as maintaining this perceptual vigilance and preventing recovery prestimulus levels of arousal.⁸² A marked heightening of perceptual vigilance may become maladaptive, since excessive vigilance may be accompanied by perceptual distortion and a preservation of defensive responses to novel but relatively innocuous stimuli. It is hypothesized that a reduction of cerebral vigilance may mediate the effects of a variety of anxiety control techniques.

With this understanding of anxiety and its measurement, a number of approaches to anxiety management in the pedodontic context will now be reviewed.

Dental Anxiety in Children: Techniques for its management

There is a pressing need for an effective pedodontic technique that will reduce fear and anxiety, encourage cooperative behavior, and facilitate the child's positive interpretation of the dental experience. As pointed out by Chambers²¹, a plethora of management techniques are currently advocated in the dental literature. However, many techniques commonly suggested for pedodontic practice are extrapolations from the clinical psychological, psychiatric, and medical fields. Typically, there exists considerable empirical documentation for the effectiveness of these techniques in their field or origin. However, ample demonstration of their utility in pedodontic applications is often lacking. Frequently, the effectiveness of such management techniques is supported by the subjective accounts of individual clinicians successfully applying the recommended technique. Occasionally, the effectiveness of techniques is supported by case history data. Even more rarely, an isolated short-term experiment performed in the pedodontic context will be reported.

Strategies for effective communication are an important element of the child management repertoire. The widely used Tell-Show-Do approach⁹¹ is one out-growth of the search for communication techniques appropriate for the young child. Several recent theoretical papers discuss useful dental applications of the psychology of communication.^{24,92,93}

Behavioral modification procedures based on operant conditioning principles have found already acceptance in pedodontic practice. In behavioral modification, the systematic application of differential reinforcement contingencies is used to shape desirable behavior and to reduce inappropriate behavior. Kohlenberg et al.⁵¹ developed a behavioral modification program to increase the frequency of three cooperative behaviors in resistive mentally retarded patients. Subjects exposed to the program more frequently exhibited the target "mouth-open" behavior and less frequently required physical restraints than did control subjects. Sawtell et al.²² failed to document an effect of a brief behavior modification procedure on children's cooperation during their first dental appointment.

Desensitization is another technique adopted from the behavior therapy arsenal. In desensitization the child is gradually and progressively exposed to graded series of stimuli increasing in their anxiety-provoking value. Osgood⁹⁴ exposed 36 dentally anxious children to a series of desensitization visits and reported a gradual diminution of anxiety. An average of 7.7 desensitization visits were required to produce an acceptance of local anesthesia and cavity restoration. Machen and Johnson⁹⁵ reported that preschool children given 30-minute desensitization session with a therapist behaved significantly less negatively during restorative treatment than children in a control group. In an earlier study Johnson and Machen⁹⁶ were unable to document the effectiveness of a single 20-minute desensitization session in which anxious children were exposed to a standardized presentation of dental instruments and

procedures. Similarly, Higgins et al.⁹⁷ and Sawtell et al.²² reported that a desensitization procedure was not superior to a placebo condition consisting of a brief period of friendly interaction with a dental assistant.

The imitative or model learning paradigm has been applied to pedodontic practice. In this paradigm, subjects are exposed to a live or videotaped model undergoing dental experiences and emitting adaptive behaviors; the expectation is that subjects will use this vicarious experience to incorporate the desirable behaviors. Several studies report results consistent with this expectation;^{35,96,97} other researchers concluded that a modeling condition was no more effective than a simple placebo condition.^{22,97}

Physical restraint is probably the most commonly used technique for the behavioral management of young dental patients. A survey of diplomates of the American Academy of Pedodontics indicated 84% used physical restraint for child management. The Hand-Over-Mouth technique is widely regarded as a useful technique.^{18,99} Physical restraint serves to protect the child and dental personnel from injury and to forcibly terminate uncooperative behavior. While physical restraint renders the child more amenable to treatment, adequate studies have not been conducted to ascertain whether this procedure actually modifies the child's dental anxiety and his/her response to subsequent dental visits.

Premedication is another widely used child management technique; 85% of pedodontists report employing premedicating drugs such as narcotics, barbiturates, and tranquilizers.⁹⁸ Nonetheless, pre-

medication has several serious disadvantages. Appropriate drug dosages are difficult to determine for young children. The drug effects, particularly with oral sedation, are often slow and unpredictable; elimination and recovery likewise are slow and variable.¹⁰⁰ With many sedative agents, it typically proves difficult to increase the dosage without producing general anesthesia.¹⁰¹ Several authors^{18,20,23} have criticized the routine use of premedication for pedodontic patients. These workers claim that premedication, while producing a more manageable child, does not remediate the fundamental problem of patient apprehension. Again, adequate empirical data are lacking to determine the effectiveness of premedication in facilitating patient management and allaying the child's anxiety.

In summary, all of the techniques discussed above present significant drawbacks to their routine application. None of the techniques are supported by a sufficient empirical base to establish their effectiveness. Most techniques currently recommended require considerable dedication and expertise on the part of dental personnel; some require specialized training and/or the collaboration of non-dental personnel. Certain techniques, while time-consuming, have proven disappointingly unreliable in initial empirical tests. All of the advocated procedures have proven clinically useful in controlling unmanageable children; however the most important issue, the longer-term effect of these management techniques on patient anxiety and attitude, has been essentially neglected.

Still urgently needed is a child management technique empirically shown to satisfy certain fundamental criteria: 1) enhancement of the

efficiency and work quality of dental personnel; 2) ease and practicality of integration into office or clinic practice; 3) reduction of patient discomfort; 4) alleviation of patient anxiety and facilitation of coping skills; 5) protection of the child's self-esteem; and 6) encouragement of a positive attitude toward dental care.

A growing number of pedodontists advocate the use of nitrous oxide as a behavior management approach potentially satisfying these criteria. The routine application of N_2O is now widespread in many parts of the U.S. Surveys^{98,102} of pedodontic diplomates report 35% and 73% using nitrous oxide to control behavior and reduce fear in 1972 and 1981, respectively. Another survey of pedodontists¹⁰³ found 44% using nitrous and an additional 12% planning to use it in the future. Seven percent reported using N_2O as their sole pharmacologic agent for child management. Asked their reason for using nitrous oxide, 48% cited patient management considerations and 31% claimed improved patient attitudes toward dentistry.

Langa's text¹⁰⁴ discussed the use of nitrous oxide analgesia and sedation in dental practice. Langa noted that N_2O is highly effective in reducing or eliminating pain. Its potential for altering the patient's emotional status is still poorly clarified. However, Langa claims that the successful dental application of N_2O is based in its clinical effectiveness in reducing anxiety and producing a sense of well-being.

Sorenson and Roth¹⁰⁰ have also discussed the advantages of N_2O from a clinical perspective. These authors stressed the ease and

safety of nitrous administration, permitting reliable control of dosage and sedative effect. Children were reported to accept nitrous administration positively. Nitrous oxide analgesia was suggested as a valuable aid to patient management, rendering dental treatment acceptable to the apprehensive child.

Similarly, Pruhs and Williams¹⁰⁵ assert that nitrous oxide has value in eliminating the child's negative emotional responses to dentistry. These authors believe that nitrous oxide administration during initial dental visits will reduce emotional distress, facilitate communication, and assist the apprehensive child in acquiring a realistic understanding and acceptance of dental treatment. These cognitive and emotional gains permit later treatment to be accomplished without nitrous oxide use.

While several authors cited above have strongly advocated the usefulness of nitrous oxide analgesia in pedodontic management, none have presented substantive data supporting their clinical impressions.

Empirical Studies of The Effects and Effectiveness of Nitrous Oxide

There exist only a limited number of studies documenting the effects of N₂O on children. No studies have been designed to provide empirical support for the diverse clinical claims related to anxiety reduction and enhanced coping abilities.

Berger et al.¹⁰⁶ assessed the analgesic effects of nitrous oxide in 21 children, 5 to 11 years of age. Analgesia was assessed by stimulating the maxillary primary cuspids with an electric vitalometer. For each child, stimulation thresholds were measured under two

control conditions (no nasal mask - breathing room air; nasal mask-administration of 100% O₂) and 3 nitrous conditions (administration of 20%, 30%, and 40% N₂O). Thresholds were significantly increased with 40% N₂O administration; threshold increases were not significant at the lower concentrations.

Hogue, et al.¹⁰⁷ studied responses to N₂O in 47 children, aged 6 to 12 years. Thirty-three children were administered N₂O; the remaining 14 children served as controls and were given 100% oxygen for an equivalent time interval. Each child in the N₂O condition was exposed to 5, 10, 20, 30, and 40% N₂O, then 100% O₂. Analgesia, heart rate, nausea, and memory loss were assessed. Analgesia was measured using a Burton Vitalometer to stimulate the mandibular left central incisor and the interdental papilla between the mandibular central incisors. Amnesia was assessed by showing the patients various objects and picture postcards during nitrous exposure. Tooth sensitivity decreased as nitrous oxide concentration increased. Heart rate did not differ between the nitrous and control groups. Neither nausea nor amnesia were observed with nitrous exposure.

Rubinstein¹⁰⁸ evaluated effects of N₂O on the perceptual psychomotor, learning, and memory performance of healthy children aged 7 to 13 years. Control subjects breathed room air through a nasal mask; experimental subjects received 35 - 40% N₂O. Eleven psychological tests were administered to assess visual and auditory perception, perceptual-motor skills, learning, and memory. Tests were given prior to inhalant administration, during administration, immediately after discontinuing inhalant, and 30 minutes after

discontinuation. Perception, learning, and memory appeared unaffected by nitrous administration. Psychomotor performance was impaired during nitrous exposure, but recovered rapidly upon its discontinuation.

Nitrous studies using adult subjects have been more extensive and have produced substantive results pertinent to this review.

The safety and effectiveness of N_2O in reducing pain has been well documented. Historically, nitrous oxide ranks among the oldest of inhalation anesthetic agents; its effects were first described by Priestly in 1776. Humphry Davy in 1799 became the first to experiment with N_2O and suggested that it be used to relieve pain associated with surgical procedures. Not until 1844 was this concept again pursued, when a chemist, Gardner Cotton, gave a demonstration of the inhalation effects of N_2O in Hartford, Connecticut. A young man under its influence injured his leg without recognizing severe bleeding or pain. Horace Wells, a local dentist, realized the potential of this technique and persuaded Gardner Cotton to administer N_2O to him while another dentist, Dr. Riggs, painlessly removed Dr. Well's tooth. Horace Wells, one month later, demonstrated his inhalation and extraction procedure at Harvard Medical School. Unfortunately, the patient's reflex movements were misinterpreted as painful responses and his demonstration was regarded a failure until 1863, when Cotton reintroduced its use in dentistry. Five years later, Andrews combined N_2O with O_2 , and Sir Frederick Hewitt described the safety of N_2O-O_2 anesthesia by providing adequate oxygenation.¹⁰⁹⁻¹¹¹

The pharmacology and physiology of nitrous oxide has been extensively studied. N_2O is an inorganic gas capable of producing anesthetic properties. Its action is related to its great insolubility in the blood plasma; 100ml. of blood will dissolve 45 ml of N_2O .¹¹² Its most important pharmacological action is central nervous system depression.^{104,111,112} N_2O is non-toxic to any organ or tissue provided it is administered with adequate (minimum 20%) oxygen concentrations.¹¹³ Dripps et al.¹¹⁴ reported that N_2O does not cause any appreciable change in cardiac rate, output, or blood pressure unless used in the presence of a hypoxic or hypercarbic state. They also indicated that it has no effect on venous pressure. Leigh and Belton¹⁰⁹ found that N_2O neither stimulates nor depresses the circulation of pediatric patients, nor does it affect blood volume or composition. Only with continuous administration exceeding 24 hours was reversible leukopenia observed.¹¹⁶

Horkey et al.¹¹⁰ reviewed the studies concerning the respiratory effects of N_2O and concluded that a depression of respiration by N_2O per se has not been established. Uptake and elimination takes place largely through the lungs with trace amounts being excreted via the skin, sweat glands, urine, and intestinal gas.¹¹⁷ When N_2O-O_2 is used in low concentrations for analgesia, there is no suppression of the cough reflex. Eckenhoff and Helfrich¹¹⁸ studied the effect of N_2O alone and in combination with other agents. They concluded that N_2O alone was a stimulant to respiration, possibly though inducing hypoxia, and that it increased the response to CO_2 . The respiratory depression produced by narcotics and barbiturates was deepened by N_2O

in a synergistic manner. The authors theorized that N₂O might alter cellular permeability and thus change the activity or effect of the combined drugs.

Several studies have assessed possible gastrointestinal effects of nitrous oxide. When N₂O-O₂ is used in low concentrations, there is an extremely low incidence of nausea and vomiting; nor is esophageal, gastric, or intestinal peristalsis affected. Hogue et al.¹⁰⁷ reported no episodes of nausea in 47 children administered N₂O concentrations ranging to 40%. Feldman¹¹⁹ observed nausea and vomiting in less than 1% of 3,000 subjects undergoing nitrous anesthesia induction. Bodman et al.¹²⁰ reported a 14.7% incidence of gastric upset in 3,000 outpatients administered nitrous oxide in anesthetic concentrations during minor surgical procedures. Parkhouse and coworkers¹²¹ observed some degree of nausea in 58.8% of their patients, when delivering 40% N₂O. Adriani¹²² claimed that N₂O itself did not stimulate the vomit center and that most nausea and vomiting with N₂O administration was secondary to inadequate oxygenation precautions. Houck and Ripa¹²³ felt that nausea episodes were not due to N₂O per se since vomiting occurred only in patients with a prior history of gastric upset during dental treatment. These authors suggested that heavy meals within 3 hours prior to N₂O administration may account for the occasional nausea and vomiting that is observed.

The effects of N₂O on the central and peripheral nervous system have also been studied. Domino¹²⁴ states that N₂O, at concentrations of 80%, does not cause a significant change in visually evoked responses in the cortex. Henrie et al.¹²⁵ evaluated EEGs of subjects

breathing either room air or 30% N₂O; no EEG alterations were observed with N₂O administration. There is no evidence that N₂O either depresses peripheral nerve impulse conduction or affects cutaneous receptor activity.¹²⁶⁻¹²⁸ Nitrous does depress a monosynaptic spinal reflex, the H-reflex.¹²⁹ The activity of this reflex can be used to evaluate reductions in muscle tone and has been employed to assess a variety of inhalant anesthetics. DeJong et al.¹³⁰ also reported that N₂O depresses polysynaptic reflexes; depression is not proportional to the number of links in the serial synaptic chain. Recovery occurred very rapidly upon withdrawal of N₂O; normal firing rates in response to noxious stimuli returned earlier than normal spontaneous activity. Smith¹²⁷ concluded from this literature that at least part of the analgesic property of N₂O derives from its action at the spinal cord level.

The analgesic action of N₂O has been extensively studied. Chapman et al.¹³¹ concluded that 20% N₂O is as effective an analgesic as 15 mg morphine sulfate. Seevers and coworkers¹¹² were the first researchers to quantitate the analgesic action of N₂O. A specially devised needle algometer was used to evaluate thresholds of pain perception. These authors concluded that 35 - 40% N₂O was an optimal concentration, providing effective analgesia while the patient retained the ability to cooperate.

Haugen et al.¹³² assessed the analgesic effects of N₂O in nine adult male subjects. Electrical stimulation was applied to filled teeth during the inhalation of room air and of nitrous oxide in concentrations up to 50%. Thresholds were measured for just-

perceptible sensation and just-tolerable pain. Both thresholds followed a parallel course under N₂O exposure; nitrous concentrations of 40% were required to produce significant threshold elevations.

Similar results were reported by Everett and Allen.¹³³ Ten adult subjects were evaluated under 20, 30, and 40% nitrous oxide exposure. Tooth stimulation was administered using a Burton Vitalometer. Tooth sensitivity was significantly decreased only at the 40% nitrous oxide concentration. The findings of Haugen et al.¹³² and of Everett and Allen,¹³³ using adult subjects, are consistent with the observations of young subjects cited earlier.^{106,107}

Smith¹²⁷ pointed out that the precise definition and measurement of pain is difficult, since many factors are capable of modifying it. Furthermore, a variety of unpleasant experiences, though morphologically different, are typically combined under the single heading of pain. There is pharmacologic evidence, for example, that painful sensations produced by tibial pressure are neurologically different from those produced by cutaneous thermal stimuli.¹³⁴ This conceptualization implies that pharmacological mechanisms of pain relief may vary with situational context and type of pain. The pain experience can be modified by psychological factors such as anxiety; therefore differentiation between the afferent transmission and the central processing of stimuli, without consideration of their potential complex interactions, may be misleading.

Sonneschein et al.¹³⁵ presented findings compatible with this conceptualization. While varying concentrations of N₂O were administered, two thresholds were measured: the threshold at which

the stimulus was just perceptible and the threshold at which the stimulus became painful. Nitrous oxide induced an alteration in the quality of the pain. With increasing concentrations of gas, it became progressively more difficult to specify the point at which the sensation became painful. The noxiousness of the stimulus decreased, while the sensation became more diffuse. Thus, the subject's interpretation of the stimulus as painful became difficult, and the subject became less concerned with the painful stimulus.

Langa¹⁰⁴ has subjectively described the patient's experience while under nitrous influence. Smooth respiration and relaxed skeletal musculature are seen, when nitrous is administered at analgesic concentrations. Pupil size is unaltered and pupils contract normally to light. The patient retains consciousness and the eyes close only briefly. The eyelids do not resist opening and the corneal reflex is intact. After breathing N₂O for 30 to 40 seconds, the patient becomes aware of a pleasantly sweet and mild odor and of a tingling sensation in toes, fingertips, lips or tongue tip. As the analgesic level deepens, the patient may feel a warm wave suffusing his body, inducing a lethargic or drowsy feeling. Very often a humming, droning, or vibratory sensation is experienced. The patient's voice has a characteristic throaty tone, lacking its natural resonance. Neither unconscious nor fully awake, the patient knows of things taking place about him, but with diminished awareness. He experiences a feeling of well-being, of safety, of euphoria. Perception of sound occurs distinctly, yet distantly.

Devine and coworkers¹³⁶ have more rigorously and objectively

evaluated the pain reducing and calming properties of nitrous oxide. Patient and dentist expectations, which may play a major role in clinical findings, were controlled. Fifty-four undergraduates were assigned to three conditions: nitrous oxide, placebo, or control.

In the nitrous condition, subjects were exposed to 40% nitrous oxide for the duration of the experimental procedures. In the placebo condition, subjects were given an initial dose of N_2O which was then surreptitiously discontinued; test procedures were administered while breathing O_2 . No mention of drugs was made in the control condition. Each subject was given a standard series of shocks increasing in amperage and was asked to report three thresholds: the first perceptible sensation, first painful sensation, and tolerance limit (when he wished the series to terminate). The subjects also reported ratings of degree of relaxation and of painfulness of the final stimulus. There were no significant differences among groups in sensation threshold; however, pain and tolerance thresholds were significantly higher in the nitrous group than the placebo and control groups. Painfulness ratings for the final shock did not differ among groups, even though the nitrous subjects were experiencing shocks of much higher amperage. Reported relaxation increased progressively from the control through placebo to drug group, with the drug group reporting significantly more relaxation than the other two groups.

Burns et al.¹³⁷ evaluated the effects of N_2O on thresholds for audition, temperature, superficial pain, touch, brightness discrimination, and proprioception. All thresholds except proprioception were elevated under nitrous.

Hammond¹³⁸ studied the analgesic effectiveness of N₂O to permit simple non-pulpally involved restorative procedures to be performed in child patients without local or regional anesthesia. Her findings suggested that, although largely a practice discouraged by the majority of pedodontists,^{102,139} adequate analgesia may be produced to preclude the noxiousness and sequela of local anesthesia for needle phobic patients.

A number of studies have examined subjects' experience of time while under nitrous influence. Westerlund et al.¹⁴⁰ administered auditory stimuli during nitrous exposure, and observed impairment in the subjects' estimation of time and ability to place auditory events in a correct chronological sequence. Steinberg¹⁴¹ found no alteration of time perception with administration of 10% nitrous. Burns et al.¹³⁷ observed that estimated time was consistently less than real time under nitrous concentrations ranging from 20 to 45%. The discrepancy between real and estimated time increased with increasing concentration of N₂O. This disturbance in time sense was attributed to the generalized elevation of sensory thresholds produced by N₂O. Greenberg et al.¹⁴² suggested that the disturbance of time sense is least apparent when subjects are rapidly brought to full consciousness.

It is commonly believed that nitrous oxide produces amnesia. However, great individual variation apparently exists, ranging from no amnesia to complete and even retrograde amnesia.¹²⁷ Brice et al.¹⁴³ describe cases where memory loss was recovered several days later. Much of this observed variation may be related to level of analgesia

or anesthesia. Malkin and Eisenberg¹⁴⁴ found no amnesia in subjects exposed to Guedal's Stage I analgesia.¹⁴⁵ Subjects demonstrated excellent cerebation when asked questions requiring a high degree of thought and memory. Hogue et al.¹⁰⁷ exposed 47 children to visual stimuli while under nitrous concentrations ranging from 5 to 40%; complete recall was observed.

Parkhouse et al.¹⁴⁶ evaluated mental performance and later recall in subjects exposed to either compressed air, 20, 30, or 40% N₂O. Mental impairment increased as nitrous concentration increased. Nitrous exposure did not have a measurable effect on delayed recall for designs and syllables. Nitrous oxide appeared to produce an impairment of delayed recall of a story, but only when 40% nitrous was administered.

Trieger et al.¹⁴⁷ used a modification of the Bender Motor Gestalt test to evaluate the effects of nitrous oxide on psychomotor abilities. Concentrations ranging from 25 to 75% were administered. The test was presented prior to induction, during nitrous exposure, during 100% O₂ administration, after terminating N₂O, and 2 and 4 minutes after terminating O₂. Impaired coordination and psychomotor function was seen after 1 minute of nitrous exposure; impairment peaked after 5 minutes of nitrous administration. Decrements increased with increasing nitrous concentration, peaking at 70% N₂O. Psychomotor effects were rapidly reversible, disappearing within several minutes after terminating N₂O.

A similar study was performed by Ayer and Getter.¹⁴⁸ Eighty-two patients, ranging in age from 17 to 50 years, were studied during a

dental treatment visit. Forty-one patients received treatment under local anesthesia; the remainder received local anesthesia plus 35 - 40% N₂O. The Reusch color test and a pegboard test were given before, immediately after, and 20 minutes after dental treatment. No significant psychomotor impairment was found as a function of the preceding nitrous administration.

The clinical implications of these diverse findings will be developed below.

Evaluation of the Potential Usefulness of Nitrous Oxide in Pedodontics

The preceding review provides ample documentation for the safety, practicality, and analgesic effectiveness of nitrous oxide in pedodontic applications. Ease and controllability of administration are significant advantages; dosage and sedative effect are readily and accurately modulated. Onset of action is rapid; excretion is also rapid, rendering recovery time minimal. Side effects of nitrous oxide are minimal, and contraindications to its use are rare.

The analgesic properties of nitrous oxide are well documented; not only are pain thresholds elevated, but the aversive quality of the pain stimulus is diminished. These observations suggest that nitrous administration would contribute to reducing the pain or discomfort experienced in dental procedures.

The ability of nitrous oxide to induce a sensation of relaxation is also well established. However, as the foregoing review reveals, the capacity of nitrous oxide to reduce fearfulness has not been adequately researched. In light of the relaxation and pain relief

produced by nitrous, it seems reasonable to hypothesize that inhalation administration would reduce the dental patient's anxiety and improve his/her general managability. Indeed, a number of clinicians have suggested that nitrous oxide alleviates anxiety and facilitates cooperation of apprehensive patients.^{104,108,136} This clinical impression remains to be documented by future systematic study.

Perhaps even more important than the problem of managing a child patient and his anxiety during a particular treatment visit is the issue of the patient's enduring attitude toward dental treatment. This concern necessitates a consideration of the effect of nitrous oxide administration on the child's behavior and anxiety at subsequent dental visits. Any technique which will foster the development of the child's coping skills and augment the child's stress tolerance would be a welcome addition to the pedodontic armamentarium. Some clinicians have claimed such an effect for nitrous oxide administration; Langa (1976) asserts that children introduced to dentistry with N₂O become excellent patients, cooperative and motivated for treatment. There is, to date, no experimental support for an effect of nitrous oxide on behavior and attitudes at sequential dental visits. However, certain findings suggest the plausability of such an effect. Under nitrous oxide, the child remains conscious and aware of ongoing events; learning and memory are essentially unimpaired; and the child undergoes a subjectively pleasant experience. These findings support the hypothesis that, under nitrous oxide analgesia, a positive learning experience may occur that will facilitate the acquisition of coping skills and a positive dental attitude.

Lacking a rigorous experimental investigation, this hypothesis remains a controversial one. A number of clinicians have argued that patient sedation is a palliative procedure of convenience, merely enabling treatment to be conducted efficiently without ameliorating the child's fundamental apprehensions.^{18,20,23} Chambers^{20,21} asserts that drug administration does not resolve the child's anxiety, but merely postpones his/her opportunity to confront the inevitable problem. The child is permitted to artificially avoid the anxious situation, preventing the opportunity to unlearn dysfunctional emotional responses and to learn effective coping strategies for managing fear reactions. The drug-exposed child is, Chambers speculates, denied the opportunity to learn that his/her undesirable coping strategies are not necessary or even useful. Therefore, when the drug is discontinued, the child remains as fearful and unmanageable as he/she was initially. Thus, a dependence on the drug is fostered and the child acquires a belief that drugs are needed to cope with stressful situations.

Inadequate data are currently available to resolve this controversy. A careful longitudinal study of the impact of nitrous oxide administration on dental anxiety during sequential treatment visits is vitally needed. A paradigm for assessing the effects of nitrous oxide on children's response to dentistry is developed in the ensuing sections.

3. Rationale

Research which attempts to evaluate the effectiveness of an anxiety management technique should emphasize a longitudinal, inter-

active approach to childhood dental anxiety, consider the role of the child, the experience, and the process by which the child interacts with his/her environment during experience. Previous studies of the etiology of dental anxiety have primarily used a retrospective approach, examining the reported histories of dentally anxious and nonanxious adults. This approach can only minimally contribute to an understanding of how dental anxiety is modified or ameliorated. Current research on the management of childhood dental anxiety has largely been limited to short term evaluation of a single brief intervention. This approach too seems inadequate to clarify the ongoing process of interaction between child and environment in determining and altering anxiety. It may be concluded that a longitudinal approach which analyses the anxiety process prospectively is needed to counteract these deficiencies.

Results reported from a longitudinal study of children's responses across a series of 6 dental visits⁵ found an initial deterioration in behavior; however, with further visits, the children's response became increasingly positive. These data indicate that dental anxiety is modified in a complex manner over the course of experience. These findings support contention that research evaluating techniques of dental anxiety management must use a longitudinal design which considers the effects of sequential experience.

The child's introduction to dentistry may be viewed as a stressful experience which mobilizes the child's coping dispositions and strategies. Through deployment of coping strategies, the child interacts with his/her experience; the outcome of this process is some

modification of the child's dental anxiety. Clearly, the outcome will be determined both by the nature of the experience and by characteristics the child brings to that experience. Therefore, both components must be considered in research evaluating dental anxiety and its management.²⁹

It is suggested that the child's response to an initial dental stress is determined by complex experiential and personality variables. Aspects of personality felt particularly salient to initial dental anxiety are: a.) the child's characteristic level of fearfulness or emotionality in relation to his/her environment, and b.) the child's characteristic cognitive style in perceiving and evaluating a novel situation. The child's emotionality level will determine whether the novel experience is approached in relaxed or fearful way; whereas the child's cognitive style will determine his/her selective perception of novel environmental stimuli.²⁹ For example, some children are very open to new information, enter into active exploration of novel environmental stimuli, and update their attitudes and feelings as this information is processed. Other children selectively perceive the stressful stimuli, exaggerate the threat posed by these stimuli, and resist information directed toward a more realistic appraisal of the threatening stimuli.

The cognitive process model of anxiety²⁷ is useful in understanding children's variable responses to dental stress. According to this theory, anxiety is a state of undirected arousal initially induced by the perception of threat. Anxiety represents a non-specific response to a situation which appears at once threatening and

ambiguous. Optimal levels of anxiety activate an ongoing process of appraisal and reappraisal, involving information collection and continuing evaluation of the situation. When adequate data have been collected to identify an appropriate course of action, energy is channeled into a coping response and anxiety is reduced. When anxiety is mild, a constructive vigilance is produced which contributes to the appraisal and coping process. However, if anxiety is severe, attention may be selectively focused on a few cues which are initially perceived as particularly threatening. The ongoing appraisal process may thus be impeded, and perceptual distortions occur. An inappropriate or premature course of action may be chosen, based on these misperceptions. Inflexible defense mechanisms may be activated, which impair the development of more appropriate coping skills.

From this perspective, repeated dental experience provides the child an opportunity to gain familiarity with the situation, to gradually acquire more accurate information about dental procedures, and to develop coping skills. However, since this experience interacts with the child's internal characteristics, there will be some children whose entry level characteristics will either limit their ability to use dental experience to develop coping skills or will predispose towards the acquisition of maladaptive strategies.

This conceptualization suggests that moderately high anxiety will cause the child to distort the danger posed by treatment and to magnify the threatening and painful nature of dental stimuli. Consequently, the anxious child will cope less effectively with dental stress and will be impaired in the ability to utilize his/her

experience to develop coping skills for mastering the anxiety.

Such a child may actually develop progressively heightened anxiety and uncooperative behavior across treatment experiences. Active and effective intervention may therefore be needed for the dentally fearful child to accurately perceive dental stress and to acquire a more positive and realistic attitude toward treatment.

The potential value of nitrous oxide in helping the anxious child adapt to treatment has emerged from the review of the literature. Clinical experience strongly suggests that nitrous oxide reduces the child's fearfulness of and improves his/her attitude toward dental treatment. Although a rigorous empirical test of this claim has not appeared, the hypothesis seems to have sufficient merit to warrant undertaking this investigation. Careful research seems particularly urgent since nitrous oxide has currently acquired widespread use in pedodontic practice, despite a particular dearth of studies in children.

This project was designed to provide longitudinal data required to test these hypotheses.

B. SPECIFIC AIMS

The goal of this project was to assess the effectiveness of nitrous oxide-oxygen in reducing anxiety and encouraging cooperative behavior in young dental patients. This global objective can be broken down into the following specific aims:

1. To assess the short term impact of nitrous oxide-oxygen on the child's response to a dental treatment visit. It was hypothesized that nitrous oxide would be an effective child management

tool; prediction was that children receiving nitrous oxide during a treatment visit would exhibit less anxiety, physiological arousal, and uncooperative behavior than children in appropriate control conditions.

2. To examine the longer-term effect of nitrous oxide-oxygen on the young patient's response to a series of dental visits. It was expected that, relative to the control conditions, nitrous oxide administration would accelerate the shift toward a more positive response over sequential visits.
3. To explore the need for continued use of nitrous oxide-oxygen. It was predicted that the acquisition of appropriate coping skills would be facilitated by the administration of nitrous oxide. These coping skills should reduce and eventually eliminate the child's need for nitrous administration. It was therefore expected, when nitrous oxide use was discontinued, children with a history of nitrous exposure would continue to exhibit less anxiety, uncooperative behavior, and negative attitude than children without nitrous experience.

C. MATERIALS AND METHODS

1. Subjects

Subject Characteristics

Subjects included in this study were drawn from the pool of patients requesting treatment at the Pediatric Dental Clinic of the University of Connecticut Health Center. These patients represented a range of socioeconomic status and ethnic background reflective of the composition of the local community.

Recruitment was based on information obtained at a brief Screening Visit (see below). Specific behavioral, dental, and medical health criteria were used in choosing potential subjects. Selected subjects:

- a.) Ranged in age from 48 to 72 months,
- b.) had no dental experience prior to the Screening Visit,
- c.) presented carious lesions requiring four treatment visits to restore,
- d.) during the Screening Visit, exhibited at least moderate dental anxiety on screening measures described below,
- e.) were free of medically diagnosed psychiatric, neurologic, cardiovascular, or respiratory disorders; children who were mouth breathers, who presented a history of vomiting, or who were on medication were excluded.

Screening Visit for Potential Subjects

Periodic Group Screenings were held at the University Pediatric Dental Clinic. A standard medical history was completed for each child presenting at these screenings. These history forms were reviewed to identify children aged 48 to 72 months, with no previous dental experience, and with no medical contraindications.

For these children, the Parental Questionnaire, and Behavioral Screening Instrument were used to assess dental anxiety. These two measures, described below, were completed utilizing a standard screening process intended to provide an objective selection of dentally anxious subjects.

The parent completed the Parental Questionnaire in the waiting area prior to the oral examination. The child and parent were then brought to the dental treatment room. The child was seated in the

dental chair and the operator completed a brief oral exam using only a mirror. Using the behavioral Screening Instrument, a trained observer recorded the child's entry and orientation to the room and his/her response to the seating and examination process. Parents whose children satisfied all selection criteria were invited to participate in the study. A full description of procedures were given and voluntary informed consent was obtained in writing from 35 subjects. A total of 1050 subjects had been screened to identify subjects with sufficient anxiety and dental treatment need.

Dental Anxiety Screening Measures (Appendix I)

The Parental Questionnaire is designed to identify children who would be expected to manifest anxiety during dental treatment. Certain items are modifications of questionnaire items constructed by Johnson and Baldwin ¹⁴⁹ and by Wright and Alpern.¹⁵⁰ The questionnaire intended to tap variables which have been identified in prospective studies, as predictive of children's anxious behavior at initial dental visits. Variables were also incorporated which, in retrospective studies, have been identified as contributory to the etiology of dental anxiety. These studies and the relevant predictive and etiological variables have been reviewed above.

Parental responses to the questionnaire provide information regarding: the family's dental attitudes and experiences; the parent's prediction of the child's behavior and anxiety; the child's medical experiences and attitudes; and the child's knowledge and perception of dentists and of his/her dental status. Each item is scored on a 1-3 point scale, giving all items an equivalent potential weight; item scores were summed to yield an overall Parental Questionnaire score for each prospective subject.

The Behavior Screening Instrument lists seven discrete objectively defined and mutually exclusive behaviors which a child might manifest during a brief oral examination, and which are characteristic of children commonly described in the literature as "anxious", "apprehensive", or "uncooperative". Each behavior was given a weight of 0 to 2, depending on whether it was observed to be "absent", "mild or brief", or "severe or persistent". Weights were summed across each behavior to yield a total behavioral score for each prospective subject.

For inclusion, the child must have achieved the following minimum scores on each screening measure:

- a.) 20 or above (out of a possible 33) on the Parental Questionnaire,
- b.) 4 or above (out of a possible 14) on the Behavioral Screening Instrument.

2. Experimental Procedures

Experimental Design

Using a computer-generated random sequence, subjects were assigned to one of three treatment conditions: an experimental group (III) which received N_2O-O_2 through an inhalant delivery system; a placebo group (II) which received O_2 alone through the inhalant apparatus; and a control group (I) which was not exposed to the inhalant apparatus. The responses of children under the three conditions were evaluated over a series of six dental visits. The basic paradigm is presented below in tabular form:

Basic Design of Research Study

VISIT	TYPE OF VISIT	GROUPS		
		I (N=11)	II (N=13)	III (N=11)
1	Examination Prophy-Fluoride			
2	Restorative Treatment 1		O ₂	N ₂ O-O ₂
3	Restorative Treatment 2		DOUBLE	BLIND
4	Restorative Treatment 3		↓	↓
5	Restorative Treatment 4			
6	Examination Polish-Fluoride			

As the table illustrates, children were exposed to the experimental inhalant conditions only during Restorative Treatment visits 1, 2, and 3. All subjects were treated according to a standard protocol across all 6 visits. (See "Dental Visit Protocol" below). Groups differed only in those procedures specific to the inhalant administration conditions. (See "Inhalant Delivery Protocol" below).

Dental Visit Protocol

Dental care for all children was provided by the same operator (principal investigator). The initial visit consisted of a standard examination which included an oral exam, prophylaxis, and topical fluoride application. Restorative dental treatment following a quadrant approach employing placement of a topical anesthetic, local anesthetic injection and isolation using rubber dam were provided for all subjects at the subsequent four visits. During the final visit, all restorations were polished, a prophylaxis and topical fluoride application were performed. For each child, visits were scheduled at weekly intervals. Subjects were referred to the Oral Radiology Department for their radiographic needs.

At each visit, self-report, behavioral, and physiological data were collected to provide a comprehensive assessment of the children's response to their dental experience. Self-report data was obtained using the Human Figure Drawing and the Venham Picture Selection Task. Behavioral endpoints included scores on the Clinical Ratings of Anxiety and Cooperative Behavior. Physiological measurements included Heart Rate & Skin Conductance. Procedures for collecting and analyzing these data are described below (see Section 3, "Procedures for Data Collection and Reduction", and Section 4, "Statistical Analyses").

At the beginning of each visit, the dental assistant escorted the child to the operatory. The child's parent was invited to accompany him/her and to remain in the operatory during the ensuing dental procedures. The child was seated in the dental chair and allowed to orient him/her self to the dental environment. During this process, the dental assistant engaged the child in pleasant conversation.

The electrodes required for physiological measurement were then introduced. The dental assistant presented electrode attachment in the context of a game, inviting the child to pretend he/she is a "robot" or a "bionic man/woman". Skin conductance electrodes were placed on the non-dominant hand, and cardiac electrodes on the child's chest and upper abdomen. Electrodes were attached using electrode cream and adhesive discs. The cardiac electrodes were introduced last; our experience indicated that the child is best able to accept the cardiac electrode application as a non-threatening event when he/she has already adjusted to electrodes being placed on the hand. Several feet of slack in the hand electrode cables allowed the child

sufficient mobility to touch his/her head; thus, the electrodes did not create discomfort or tension by physically restricting the child's limb movement. The entire attachment procedure was accomplished in an unhurried manner which provided the child ample opportunity to assimilate the experience. The process is designed to minimize the extent to which the recording procedures themselves elicit the child's anxiety. Our experience has been that children enjoy and participate in the process and quickly learn to do much of the electrode attachment themselves.

The child was asked to rest his/her hand in the lap, to avoid dislodging the electrodes during the dental visit. Should the electrode contact be disturbed at any time, the psychophysiological monitoring the polygraph would notify the chairside assistant. The electrode would then be replaced and the child reminded to rest his/her hand in the lap.

Following the electrode attachment, a short period was required for calibration of physiological equipment, stabilization of the recording, and measurement of baseline levels. The child then performed the Human Figure Drawing Task and the Venham Picture Selection Task.

After completion of the self-report tasks, the dental assistant attached the napkin and reclined the dental chair. The dentist then entered the operatory and the scheduled dental procedures were performed.

Each dental visit was segmented into periods corresponding to specific dental procedures. The specific periods defined for each

type of visit are presented in tabular form below. A one-minute resting period immediately preceded each dental procedure period. The child was instructed that, "Now you can take a minute to sit back and relax. Just rest for a minute."

Concurrent behavioral and physiological data was obtained within each period, as described in detail below (see Section 3, "Procedures for Data Collection and Reduction"). This procedure takes into account previous findings that various dental procedures elicit significantly different responses from children.^{6,22}

Specific Dental Procedure Periods Within Dental Visits

<u>Exam Visit</u>	<u>Treatment Visit</u>	<u>Polish Visit</u>
Seating/ Orientation *	Seating/ Orientation *	Seating/ Orientation *
Mirror/Explorer Exam +	Mirror/Explorer Exam + Nasal Mask (N ₂ O&O ₂ groups) +	Mirror/Explorer Exam +
Prophylaxis +	Anesthetic Injection +	Prophylaxis and Polish +
Fluoride Application +	Cavity Preparation +	Fluoride Application +

* Procedure performed by Dental Assistant.

+ Procedure performed by Dentist.

While performing dental procedures, the operator attempted to maintain a consistent orientation toward patient management. This orientation emphasizes respect for the cognitive level, behavioral capacities, and emotional needs of each young dental patient. The child's emotional expression was acknowledged and tolerated, although firm restrictions were imposed regarding potentially harmful behavior.

A cooperative and positive attitude was encouraged by a gradual process which combines patience, support, and praise for appropriate behavior. Procedures were explained and demonstrated in a relaxed, unhurried way before being undertaken. This approach is intended to facilitate an accurate perception and eventual acceptance of the dental experience by the child. It was anticipated that each child would behave somewhat differently, and that the dentist's behavior would be responsive to these differences. Thus it was not possible for each child to experience identical dentist behavior. However, it was possible to standardize the dentist's behavior to the extent that the dentist responds to specific child behaviors in a similar manner across all subjects.

Inhalant Delivery Protocol

Procedures associated with the inhalant conditions were introduced on restorative Treatment Visits 1, 2, and 3. Parents were instructed in advance that the meal prior to each visit should be light and consist solely of liquids. Upon arrival for these visits, the child was briefly examined by the dentist. The absence of nasal, upper, or lower respiratory tract congestion was confirmed by inspection and auscultation. The dental assistant then seated the child in the operatory and proceeded with the protocol previously described.

On restorative Treatment Visit 1, children in Groups II and III were introduced to the nasal mask. After the Mirror/Explorer Exam, the dentist gave the child the following explanation: "Sometimes children feel scared at the dentist's. Breathing a special clean air helps these children feel relaxed and happy. This air is very fresh

and smells like flowers. It will help you relax and have fun today." The nasal mask was presented, as the child is told: "The special air comes out of this mask. This mask is just like the ones the astronauts and airplane pilots wear. I would like you to wear it, just like this." The dentist demonstrated by placing a mask over his own nose. The mask was then transferred onto the child's nose; the child was instructed to breathe through the nose while positive suggestions were made regarding the gas's effect. All communications were given in a well modulated, reassuring tone, and the entire process conducted in a relaxed, unhurried manner.

Delivery of inhalant was conducted by the trained anesthetist with the operator remaining uninformed of type and concentration of inhalant delivered. A Quantiflex MDM Analgesia System (described in Appendix II) delivered the appropriate inhalation agents. For children in the O_2 condition, 100% oxygen at a flow rate of 3 liters per minute was delivered during subsequent dental procedures. For children in the N_2O conditions, 80% oxygen and 20% nitrous oxide were initially delivered. Subsequently, the anesthetist would adjust the nitrous concentration as needed to produce optimal levels of relaxation and cooperation. The operator would strive to maintain the child in Plane 2 of analgesia (see Appendix III), a state in which the child is relaxed but still able to cooperate. From the initial concentration level of 20% N_2O , concentration was raised in 10% increments as needed, to a maximum concentration of 50%. A minimum one-minute interval separated each concentration increment. Once the child had achieved a relaxed state, the minimum nitrous concentration required to maintain this state was delivered during the duration of dental

treatment. Thus, following nitrous induction and ensuing relaxation, concentration ranged from 20 to 50%, based on the changing responses of the child. Upon completion of a Treatment Visit, the nitrous flow was discontinued; 100% oxygen, at a flow rate of 6 liters per minute, was given for a 3-minute period to prevent the occurrence of diffusion hypoxia.

A record of durations and concentrations of nitrous flow was maintained on a specially designed graph.

3. Procedures for Data Collection and Reduction

Physiological Measures

Physiological endpoints included Heart Rate, and Skin Conductance. Data recording and reduction techniques will be described below.

As discussed previously, the process of physiological recording is relatively unobstrusive and minimally stressful. It has been designed to minimize the impact of the measurement procedure per se. As suggested by Epstein,⁹⁰ care was taken to avoid any measurement process which would be stressful to the child and would therefore bias the results.

Physiological arousal was measured during an initial baseline period, subsequent control periods, and periods associated with specific dental procedures. After all electrodes were attached, the equipment calibrated, and recording stabilized, the initial one-minute resting Baseline was obtained. The Dental period data was obtained during the initial one-minute of each dental procedure (see Table in "Dental Visit Protocol" Section). The Control Period data was collected during the one-minute resting period immediately preceding

each dental procedure. A final one-minute of baseline physiological data was collected following the termination of all dental procedures.

The physiological data was simultaneously recorded on FM tape and polygraph paper. The FM tape provided permanent storage of the raw data for subsequent analysis.

Analog data was converted to digital signals by a computer automation A/D converter. Off-line processing was performed by an

Physiologic Data Intervals For Each Type Of Visit

INTERVAL	BASELINE/ EVENT	INITIAL VISIT	RESTORATIVE TREATMENT VISITS	FINAL POLISH VISIT
1	B1	Initial Baseline	Initial Baseline	Initial Baseline
2	E1	Noise "Startle Reflex"	Noise "Startle Reflex"	Noise "Startle Reflex"
3	B3	Baseline	Baseline	Baseline
4	E3	OHI	OHI	OHI
5	B4	Baseline	Baseline	Baseline
6	E4	Exam	Exam/Mask Introd.	Exam
7	B5	Baseline	Baseline	Baseline
8	E5	Prophylaxis	Topical Anest.	Prophy/Polish restorations
9	E52	-	Local Anesthesia	-
10	B6	Baseline	Baseline	Baseline
11	E6	Topical Fluoride	Cavity Prep.	Topical Fluoride
12	B7	Final Baseline	Final Baseline	Final Baseline

alpha LSI laboratory computer, programmed to accomplish the data reduction and transformation procedures described below. The LSI computer provided output via hard copy from the on-line printer and

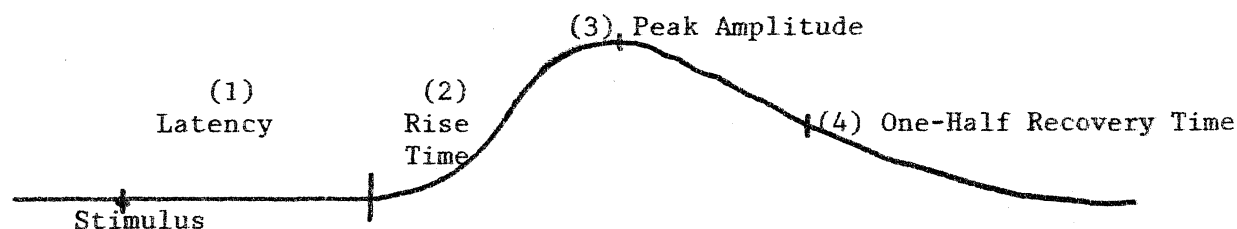
visual display on the terminal display screen. Reduced data from the LSI computer was stored on floppy disks and transcribed for coding and subsequent keypunching for statistical analysis. Coding, keypunching, and data analysis were performed at the computer center maintained by the University of Illinois at the Health Sciences Center, Chicago, Illinois.

Heart Rate Data. Heart rate (HR) measures are widely used in psychophysiological studies and are believed to reflect situational fear⁶⁰ and anxiety.¹⁵¹ Specific stressful dental procedures, such as local anesthetic administration, are accompanied by elevations in mean heart rate.^{6,152}

Beat-to-beat recordings of heart rate were obtained using a biotachometer. Measures obtained reflected the central tendency and variability of heart rate. Standard correction and transformation procedures were applied, as appropriate to the data. For each child, heart rate measures were calculated for the Initial Baseline, Control and Dental periods of each visit. The mean and standard deviation (SD) of beat-to-beat heart rate were derived for each one-minute period. Epstein's measure of HR variability⁸⁶ was obtained. Median and semi-inter-quartile range were computed in the event the data appeared extremely skewed.¹⁵⁴

A mathematical procedure developed by Nomikos et al.¹⁵⁴ was used to smooth HR data; this smoothing procedure appears to yield better concordance between SC and HR measures. Each recording period was segmented into 2.5 second intervals (approximately 4 heart beats); the maximal HR value for each interval was selected. These values are

Skin conductance responses (SCRs) were recorded on another polygraph channel. Elicited or specific SCRs have a latency of 2 to 4 seconds; therefore responses were scored as specific SCRs during the initial 10 seconds of a Dental period. The SCRs were analyzed using Edelberg's criteria,¹⁵⁷ graphically illustrated below:



The SCR with the highest peak amplitude was identified for each period; its latency, rise time, amplitude, and one-half recovery time were calculated. An estimate of total conductance power was obtained for each period by averaging all the peaks of SCR amplitude during that period. Johnson & Lubin¹⁵⁸ have developed a formula to derive the corrected proportion of elicited SCRs after spontaneous SCR activity has been determined. This technique may be employed, as well as covariate analysis (discussed below). Lykken's Range Correction Factor was also applied for the SCR where SCR_{max} is the highest

$$\Delta \phi = \frac{SCR_x}{SCR_{max}}$$

amplitude SCR of the whole session. Use of this correction factor is particularly appropriate in view of the expected individual differences in SCRs in the age range studied. Conductance power was estimated from these transformed amplitude data.

Spontaneous or non-specific SCRs were identified using Epstein's criteria;⁸⁶ a spontaneous SCR has a minimum amplitude of .5 micromhs and a maximum rise time of 1 second. Spontaneous SCR activity was to be evaluated during Baseline and Control intervals.

Significant difficulty was encountered in the recording of skin conductance. Although the literature indicates the usefulness of this measure as a fine index of situational arousal, its application in the conduct of this study posed insurmountable problems. Due to the anxiety selection criteria, differentiation between movement artifact and actual data was not readily accomplished. Since a requirement of this measure was a relatively stationary subject, the inability to prevent hand movement frequently resulted in dislodgement and/or faulty contact of surface electrodes. Substantial missing data resulted which further precluded meaningful assessment.

Additional Data Transformations. The Law of Initial Values or LIV (Lacey and Lacey, 1962) asserts that the magnitude of response to a stimulus is inversely proportional to the pre-stimulus activity level. The degree of correlation between pre- and post-stimulus level varies across individuals, across physiological endpoints, and across repeated measures of a particular individual. The LIV effect is observed both with HR and SCR activity and reflects the action of homeostatic regulatory mechanisms. A technique of Autonomic Lability Scoring (ALS) has been developed to control the influence of initial activity level on response magnitude.¹⁵⁹ A between-subjects regression analysis is used to adjust for pre-stimulus activity level. The ALS reflects the individual's response to stimulation over and above

the LIV effect; it therefore permits comparison of response patterns between individuals or across repeated measures. This scoring technique can be readily adapted to our data collection procedure, which incorporates Baseline and Control period assessment of physiological arousal.

The ALS technique may prove inadequate for our repeated measures design, since the ALS does not control for differences in the within-subjects regression. Such differences must be considered in any attempt to parcel the variance attributable to stimulus-response and individual response specificity. Since specificity is most apparent in repeated measures of stimulus-evoked responses, an adequate procedure must be applied to adjust for both LIV and specificity effects. A promising but extremely complicated multivariate analysis procedure has been reported;⁷⁶ the procedure employs a covariance analysis^{159,160} and a revised standardization method⁷³. Transformed scores are derived from a four-step procedure which includes: an initial correlation of responses with pre-stimulus levels; an analysis of covariance; a component of variance analysis; and finally, concordance analyses which assess specificity. Transformed scores can then be entered into the appropriate statistical analyses to evaluate the experimental conditions. The scope of this project and difficulties encountered in recording SC on young children precluded utilization of this format of analysis.

Behavioral Measures

Behavioral data was derived from Clinical Ratings of Anxiety and Cooperative Behavior.

Coding the dental procedures enables analysis of behavior within specific procedures as well as across the total visit. It can therefore be determined whether certain procedures reliably elicit more anxious uncooperative behaviors than others. Furthermore, it is possible that children's responses to certain specific procedures may more efficiently discriminate among the experimental conditions than responses summed across the total visit.

As such both inferential and descriptive analyses will focus upon group and individual responses during specific anxiety provoking intervals (e.g. administration of local anesthesia and cavity preparation).

The Clinical Ratings of Anxiety and Cooperative Behavior are designed to provide global qualitative assessments to the child's response to dental procedures. The rating scales are presented in Appendix IV. These scales have been used and validated in Venham's longitudinal project.

The Clinical Ratings were based on videotaped visit segments, and were made by trained judges naive to the experimental hypotheses and inhalant conditions. Video recording was done by the research assistant stationed in the control center. This laboratory member activated the videotape system to obtain a behavior sample of standard length for each dental procedure previously defined (see Table in "Dental Visit Protocol" Section).

Self-Report Measures (Appendix V)

These measures included the Human Figure Drawing and Picture Selection Task.

The Human Figure Drawing Task was presented after electrode attachment. The child was given a blank 8½" x 11" sheet of paper and a box of crayons. He/She was asked to "draw a picture of a person". The drawing was scored using a modification of Engle and Suppes' scoring system.^{41,45}

Following the Human Figure Drawing, the child completed the Picture Selection Task. The series of 8 picture pairs were presented in a randomized order. Standard instructions were given in the manner below:

"We have some pictures to show you. Here are two children. They are waiting to see the dentist, just like you are. Look carefully at their faces to see how these children feel. Pick the child who feels most like you do right now. Think about how you feel right now to help you pick the child who feels the most like you do." (Child's response.) "Thank you. Here are two more children etc."

A summary score was derived from the picture selection responses, using a method developed by Venham;⁴⁶ this score ranges from 0 to 8 and reflects the frequency with which the more anxious member of the pair is selected.

Nitrous Oxide Measures

The percentage of nitrous oxide delivered during a visit can range from 20 to 50%, depending on the child's level of anxiety; concentration parameters were expected to vary across subjects and sequential visits. A record was maintained to reflect these quantitative aspects of the nitrous exposure.

At the completion of each visit during which a nasal mask was used, a judgment of the child's inhalant condition was obtained from the dentist. These judgments were used to assess the adequacy of the double-blind procedure in maintaining the researcher's naivete.

4. Statistical Analysis

The statistical analysis was designed to test the hypotheses developed in the "Specific Aims" section. Due to the complexity of the research design, and the limited sample size inferential analysis was restricted to specific subsets of the data. Not all hypotheses of interest were expected to be addressed by statistical analysis because of this small sample size.

A three factor analysis of variance with repeated measures over the last two factors was performed. The three factors included variability across 1) Groups (between-subject variability) 2) treatment intervals, and 3) visits (over time as experience accrued.) Within subject variability was expected to add further complexity to the design and interpretation of the effects of N₂O on behavioral and physiologic responses of experimental vs. control subjects.

Given this multivariable setting, a profile was set up for each group over time, with the intent to provide a global representation of subjects responses; this would enable testing of the most important hypotheses. As such the limitations of inferential techniques could be addressed by descriptive and trend analyses.

The opportunity for identification of group differences where sample size is small is seriously limited when wide variability within individuals is encountered. Although differences may exist between groups, it is difficult to identify whether or not the difference is due simply to chance.

The first hypothesis concerned the short-term effect of N₂O on the child's response to restorative dental treatment. It was predicted that N₂O would have an immediate positive impact on behavior and arousal during the inhalant exposure (inhalant conditions imposed on visit 2). This hypothesis was evaluated by comparing responses during visit 2 across groups using a one-way ANOVA.

The second hypothesis related to the longer-term effect of N₂O administration during sequential visits. It was hypothesized that over a series of 3 restorative visits during which it was used, N₂O would facilitate a progressive reduction of anxiety and emergence of cooperative behavior. It was predicted that any positive shift would be greater and more rapid in the N₂O group than the control groups. The inhalant exposure conditions occurred during visits 2, 3, and 4. This second hypothesis was tested using a 3 factor ANOVA with repeated measures on two factors. A trend analysis was used to depict each group's response function across visits. These response functions would be compared to determine if the groups differed in direction or rate of change across sequential visits.

The final hypothesis concerned the residual effects of prior N₂O exposure. It was hypothesized that when inhalant conditions were terminated, the beneficial effects would be evident during a

subsequent visit (visit 5). One test of this hypothesis would use a one-way ANOVA comparing the three group's responses during this visit. Any change in response related to the withdrawal of the inhalant conditions might then be examined by comparing the response of each group during visit 5 to the response of that group during visits 2, 3, and 4.

D. RESULTS

The results reported below are organized in a manner to permit addressing the specific arms. Analysis of the physiologic responses, mean heart rate (HR) recorded as continuous measures, and the non-continuous self-report and behavioral observation measures are presented independently.

In the concentrations used in this study, N₂O had a significant effect on reducing uncooperative and anxious child behavior during the more traumatic procedures of a given dental visit. The results suggest that compared to control conditions, N₂O facilitated a more accurate appraisal of the degree of threat imposed by the injection of local anesthesia and cavity preparation. It therefore seems reasonable to conclude that among the effects attributed to N₂O is a genuine reduction in the aversive quality of stimuli, part of which may be mediated by its analgesic properties. N₂O may have served to reduce high levels of anxiety to milder forms which as the Lazarus model suggests, fostered a constructive vigilance which contributed to the appraisal and coping process.

Across a sequence of 3 visits, subjects receiving N₂O demonstrated and sustained more favorable responses to injections and cavity preparation compared to control subjects. In contrast to a relatively slow shift toward coping and acceptance of treatment, which previous longitudinal research suggests occurs over repeated experiences, N₂O subjects showed improvement earlier in the sequence.

With respect to the need for continued use, subjects with a history of N₂O exposure sustained lower levels of arousal, less uncooperative behavior and anxiety compared to subjects in control conditions. The marginal extent to which groups differed across the final restorative visit, however, suggests that adequate coping skills had not developed to eliminate the child's need for N₂O administration. More visits and certainly a larger sample size would enhance the ability to clarify this important issue.

Nitrous oxide was not found to significantly affect physiologic arousal either during a single visit or across sequential experiences. Trends, however, indicated that subjects receiving N₂O manifested less (not reaching statistical significance) arousal during injections and cavity preparation.

Additional findings provide insight related to placebo effects and a clinical criteria for use of N₂O on the basis of anxiety levels.

A placebo effect of the nasal mask (O₂ delivery) coupled with positive suggestion was not found to occur. On the basis of the responses of a few subjects from each group, it seems likely that N₂O alone cannot realistically be considered appropriate for management of the severely anxious patient.

As stated in the preceding section, small sample population size and wide intra- and inter-subject variation heavily impact on the

ability to demonstrate statistical significance of a drug effect. Descriptive analysis of results presented in Figures 1-9 will be helpful in providing insight and clarification of the potential effects of the experimental conditions. Although statistical significance was identified in only two tests involving the behavioral ratings, responses of the three groups tended to follow consistent patterns. Strong trends illustrated graphically appear to indicate that significant differences would have been seen had sample size been greater or variation between subjects smaller.

The screening procedures and randomization process were successful in identifying and distributing subjects with sufficient anxiety. No group differences were found for heart rate across all intervals in visit 1 ($P=0.3956$). Similarly, group differences were not found across all baseline and event intervals of visits prior to the introduction of experimental conditions at visit 2 (Table 1).

No apparent differences were found associated with birth order, social position, education or occupations of mother and fathers.

Immediate and Long-Term Effects of N₂O and the effect of its discontinuation

1. Mean Heart Rate

A consistent pattern emerging from the mean heart rate data was the extensive intra- and inter-individual variability manifested during and across visits. As such differences within and between subjects across visits and intervals within visits were significant $p<.001$ (Tables 1, 2 and 3). However, all results testing for group differences were non significant.

As a single measure of physiologic arousal believed to reflect situational anxiety, statistically significant group differences were not found to support the hypothesis of a beneficial effect of N₂O during a specific restorative treatment visit (Table 1). For visit 2, group differences in mean HR were not demonstrated given assessment across all data intervals ($p=0.8479$). Similar findings were seen for visits 3,4, and 5 across all intervals.

Table 1 3-way ANOVA with repeated measures
Mean Heart Rate Across All Data Intervals for Visits 1-6

VISIT	SOURCE	DF	TYPE I SS	F VALUE	PR>F
1	ID(Group)	32	31862.93	8.91	0.0001
	Interval	10	1581.90	1.41	0.1723
	Group*Interval	20	1304.89	0.58	0.9234
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	1901.24	0.95	0.3956
2	ID(Group)	32	34628.18	22.64	0.0001
	Interval	11	3429.59	6.52	0.0001
	Group*Interval	22	1862.88	1.77	0.0183
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	358.89	0.17	0.8479
3	ID(Group)	32	46783.34	15.10	0.0001
	Interval	11	2789.30	2.62	0.0033
	Group*Interval	22	3109.18	1.46	0.0846
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	2601.56	0.89	0.4207
4	ID(Group)	32	41506.39	16.22	0.0001
	Interval	11	1889.04	2.15	0.0169
	Group*Interval	22	1388.61	0.79	0.7396
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	134.44	0.05	0.9496
5	ID(Group)	32	54099.67	25.29	0.0001
	Interval	11	2792.22	3.80	0.0001
	Group*Interval	22	694.93	0.47	0.9808
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	877.36	0.26	0.7731
6	ID(Group)	32	26148.06	14.62	0.0001
	Interval	10	1947.01	3.48	0.0002
	Group*Interval	20	1200.11	1.07	0.3764
	Using Type IV MS For ID(Group) As Error Term				
	Group	2	26.47	0.02	0.9839

The above comparisons included samplings of all 12 intervals within a given visit. Not all intervals into which visits were divided could be expected to elicit variable group responses. Restriction of the data sampling to include the more threatening baseline and event periods could be expected to enhance the feasibility of detecting group differences. Exclusion of baseline and event intervals which occurred prior to the onset of experimental conditions (Table 2), however, similarly failed to reveal group differences reaching statistical significance.

Table 2 3-Factor ANOVA with Repeated Measures of Heart Rate for Visits 2, 3, and 4 across Intervals 5, 6, 8, 9, 11, and 12

SOURCE	DF	TYPE I SS	F VALUE	PR>F
ID(Group)	32	47443.95	16.04	0.0001
Visit	2	1516.76	8.20	0.0003
Group*Visit	4	1187.97	3.21	0.0127
Interval	5	3598.63	7.79	0.0001
Group*Interv	10	1369.21	1.48	0.1426
Visit*Interv	10	770.81	0.83	0.5961
Group*Visit*Interv	20	583.01	0.32	0.9983

Test of Hypothesis using the Type IV MS for ID(GROUP) as an Error Item				
GROUP	2	1569.75	0.53	0.5940

Further restriction of HR sampling, illustrated in Table 3 included responses over intervals 9 and 11, events of particular relevance to the clinician - the injection of local anesthesia and cavity preparation.

Table 3 2-Way Analysis of Variance of HR for Visits 2,3,4, and 5 across Intervals 2, 9, and 11

Interval 2 (Startle Reflex)

SOURCE	DF	TYPE I SS	F VALUE	PR>F
ID(GROUP)	32	20225.99	2.66	0.0001
VISIT	3	740.42	1.04	0.3794
GROUP*VISIT	6	2048.42	1.44	0.2079
GROUP	2	83.04	0.07	0.9365

Interval 9 (Injection of Local Anesthesia)

ID(GROUP)	32	15772.48	4.46	0.0001
VISIT	3	1199.73	3.62	0.0159
GROUP*VISIT	6	416.44	0.63	0.7078
GROUP	2	768.29	0.78	0.4672

Interval 11 (Cavity Preparation)

ID(GROUP)	32	18838.08	4.02	0.0001
VISIT	3	158.42	0.36	0.7841
GROUP*VISIT	6	187.33	0.21	0.9718
GROUP	2	1246.01	1.06	0.3589

Descriptive assessment of the immediate effect of N₂O on heart rate during a specific visit or its longer-term effect across sequential visits is permitted in the following series of figures. Although it is not possible to make definitive inferences regarding what constitutes clinically significant differences between groups, several findings described below are suggestive of differences attributable to a drug effect.

Figure 1 plots group mean heart rate across all data intervals for each of the 6 visits. It serves to illustrate the rank ordering, magnitude and direction of variation between groups. Fluctuations are noted relative to the rank ordering of Groups within and across visits. Not seen, however, are substantial differences in magnitude

in which to verify a positive effect of N₂O. For the greater part, the findings depicted in figure 1 are consistent with those seen statistically in Tables 1-3. Nevertheless, inspection of each visit is indicated and is described in detail below.

Except for intervals 2 (startle reflex) and 3 (baseline preceding the application of disclosing solution), variation between groups across all intervals within the initial visit appears minimal.

With the introduction of experimental conditions at interval 6 in Visit 2, groups appear to respond in a similar fashion to one another. In general, all groups displayed increases in mean HR during events and decreases corresponding to baseline periods. Although mean HR decreases in a progressive and consistent pattern over introductory intervals, distinct increases in arousal occur corresponding to the onset of more invasive procedures. Increased arousal is noted for all groups during placement of topical anesthesia, local anesthesia, and cavity preparation. No discernible difference between groups is apparent during intervals 8 and 9. However, Group III (N₂O) displays less arousal during cavity preparation compared to the two control conditions. Group I (no mask), which recorded the lowest level of arousal through the initial half of the visit, manifested an abrupt increase for later intervals compared to the N₂O condition. A similar response pattern was noted for Group II (O₂).

In Visit 3, commensurate with the baseline period preceding the onset of experimental conditions at interval 6, Group III displays the lowest level of arousal. Not surprisingly, relative increases in

mean HR are observed in both control groups similar to those seen in the previous visit. It is however, somewhat suprising not to find statistical group difference during intervals 9 and 11 in view of the plot for Visit 3.

The typical phasic responses of groups to baseline (decreases) and events (increases) was seen in Visit 4. Interestingly, given 2 previous experiences with N₂O, Group III showed higher arousal levels before the nasal mask was introduced in this visit. With the onset of more stressful procedures, a reversal in ranking occurred; Group III subsequently displayed the lowest levels of arousal. Except for during cavity preparation, the magnitude of the differences between groups was not as dramatic as had occurred in the previous visit. It is important to note at this point that a trend toward increasing levels of arousal are seen for the control conditions. The level of arousal seen for Group III was sustained at a relatively constant level, below that seen for Groups I and II. These findings appear consistent with the hypothesized results both over the course of single visit and sequential visits.

With the removal of mask conditions for Visit 5, differences between Groups II and III diminished. Groups I, however, continued to display a progressive increase in arousal during intervals 8, 9, and 11. Group I did not appear to show adaptation to stress or benefit from previous experience during the final restorative visit.

The plot for Visit 6 shows no discernible group differences. Interestingly a change in relative position of the three groups had occurred; the arousal level of the N₂O group exceeded the control

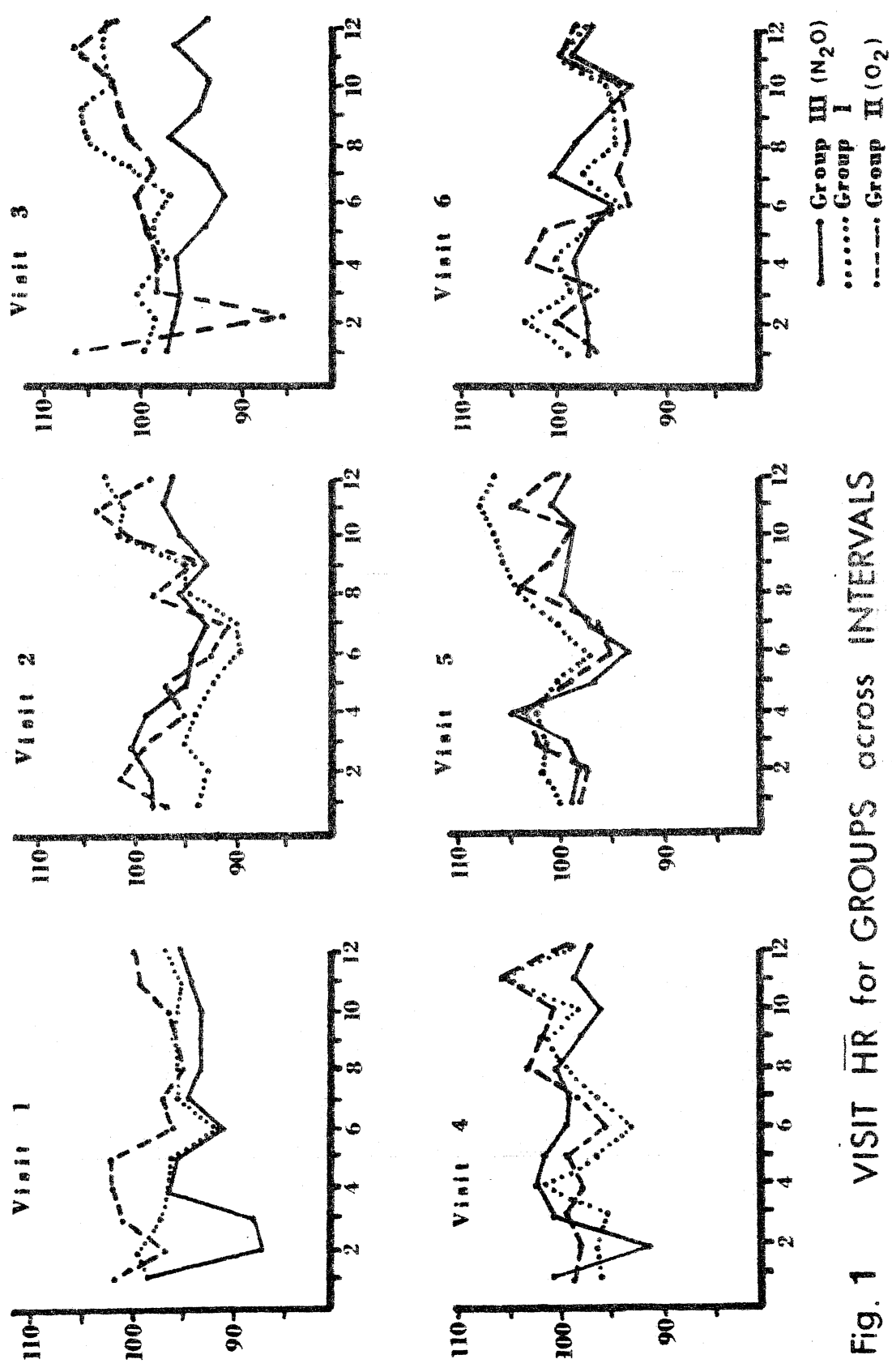


Fig. 1 VISIT $\overline{\text{HR}}$ for GROUPS across INTERVALS

conditions during intervals 7-9. Responses to the final topical application of fluoride and its pre-and-post baseline periods were essentially identical.

Figure 2 plots the sequential responses of each group across the 5 visits for specific intervals. From a clinician's perspective, if N₂O served to reduce arousal during the most stressful phases of a visit it might be possible to discriminate group differences from the graphs in Figure 2.

Interval 5 was considered a logical baseline period upon which to begin comparisons; by this stage of the visit subjects were likely to have become acclimated to the recording procedures. This assumption is consistent with previous longitudinal research which has observed anxious subjects promptly shifting their focus of attention from electrode recording procedures to the impending dental procedures. It is obvious from this plot that no detectable differences between groups exist.

Similarly, no differences can be seen during interval 6 (mirror and explorer examination) following introduction of the nasal mask. This finding tends to support the belief that application of the nasal mask alone was not a factor which prompted increased arousal or exacerbations in uncooperative behavior. Any subsequent changes in arousal might then be attributable to the perception of threat imposed by the specific dental procedure.

Trends suggestive of a N₂O effect (not statistically significant) emerge with the placement of topical anesthetic, injection, and cavity preparation. Following Visit 2, each group displayed progressively heightened arousal, assumably in anticipation

of and in response to the injection of local anesthesia. Despite minimal increases in HR during intervals 8,9, and 11, Group III remained below its counterparts. Differences between Group III and the control conditions across these procedures were greatest during Visit 3. Although to a lesser intensity, this relationship was sustained through Visit 4.

Interval 12 (final baseline) recordings found Group III displaying the lowest arousal across all visits. Consistent with the findings reported above for intervals 8, 9, and 11, the greatest variation occurred during Visit 3 with a gradual equalization across visits 4-6.

With the discontinuation of N₂O and mask conditions after visit 4, a reduction in the magnitude with which Groups II and III differed was seen during Visits 5 and 6. O₂ subjects appeared to benefit from the removal of the mask while N₂O subjects showed increased arousal. Arousal for Group I, however, intensified through Visit 6. It is unclear, however, whether or not Group II's improvement can be attributed to either (1) removal of a condition which introduced greater uncertainty and threat to coping, or (2) adaptation as experience accrued, or (3) both. The first explanation seems most plausible since Group I did not show indications of reduction in arousal.

The apparent differences illustrated in Figure 2 which find N₂O subjects displaying lower levels of arousal show promise of a favorable immediate and long-term effect of N₂O. It must be remembered, nevertheless, that these differences were not significant

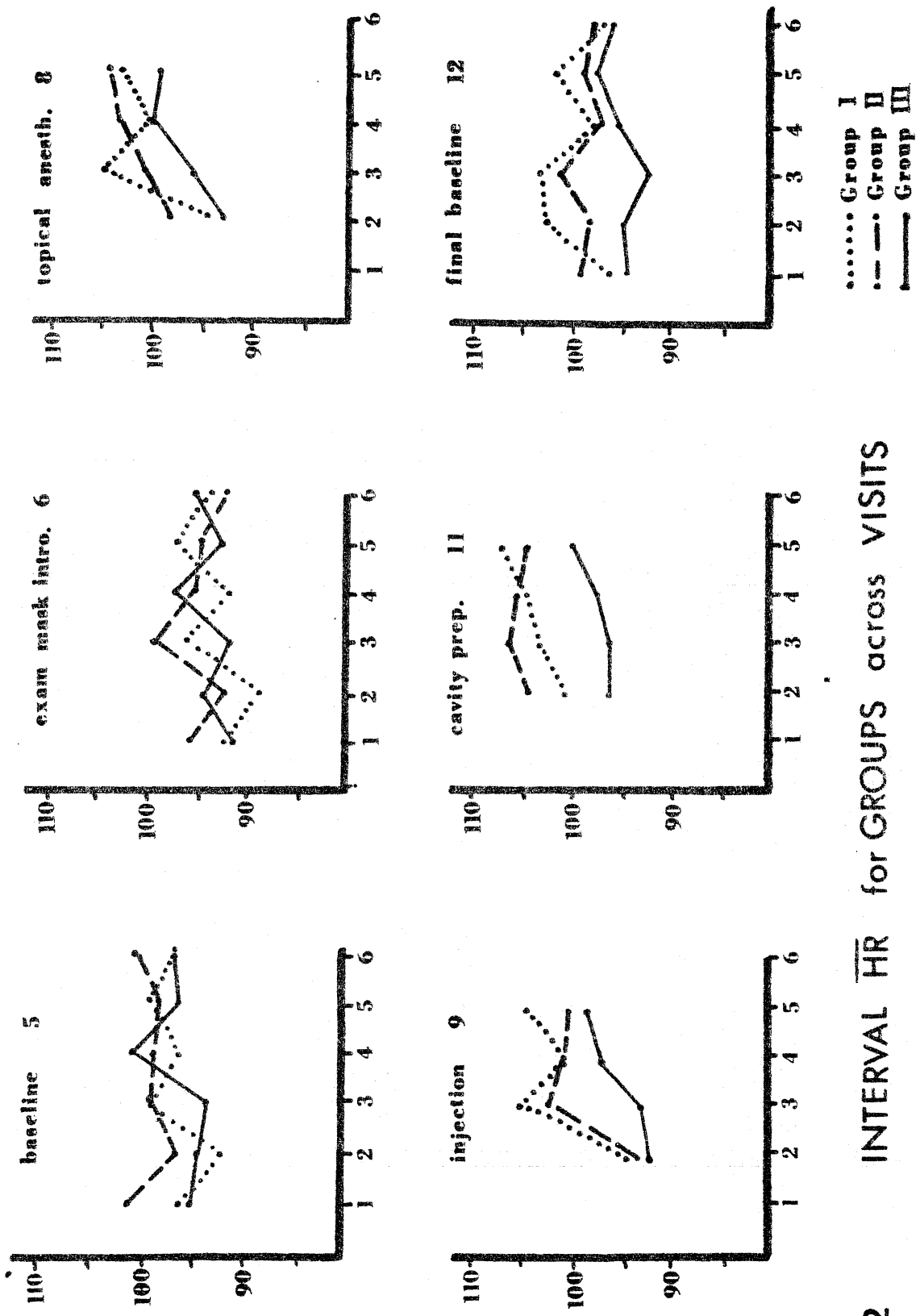


Fig. 2 INTERVAL HR for GROUPS across VISITS

statistically. Wide intra- and inter-subject variability and small sample size were inhibitory factors from a statistical perspective. As a result, the patterns noted in Figure 2 cannot be construed as sufficient to offset the probability of their occurrence by chance.

Conversely, the consistency with which N₂O subjects manifested lower arousal in response to noxious stimulation cannot easily be overlooked. The presence of differences across the observational ratings paralleling the trends observed for heart rate would reinforce our assessment of the results of the observational ratings; their implications will be discussed shortly.

Figures 3a, b, and c graph the sequential visit mean HR for Groups I, II, and III, respectively, across specific intervals of interest. Wide inter-visit variability is apparent within and between groups.

For Group I, arousal tended to be lowest during Visit 2 and increased in intensity, sometimes reaching peak levels during Visit 3. Except during cavity preparation, some reduction was seen during Visit 4. The final restorative visit frequently displayed the highest HR recordings.

For Group II, the highest arousal levels were clearly found to occur during Visit 3. With the exception of interval 8 (placement of topical) a progressive decrease in mean HR was observed after visit 3. This finding should not be surprising in view of the apprehension associated with the impending injection of local anesthetic.

In contrast to Groups I and II, the N₂O group manifested lower levels of arousal during Visits 2, 3, and 4; most striking were the differences seen across Visits 2 and 3.

Looking at the same intervals, Figures 4a, 4b, and 4c provide group comparisons of the sequential visit HR responses. The shaded portions of each bar graph identify which group displayed higher levels of arousal during a given visit and the magnitude of that difference.

Figure 4a compares Group I vs. Group III. Prior to the application of the mask and uptake of N₂O, no perceptible differences are seen as each group, almost on an alternating basis, compete for higher HR levels. Subsequent to mask placement commensurate with the onset of the more threatening dental procedures, Group I demonstrates consistently higher levels of arousal than Group III.

Figure 4b compares Group II vs. Group III. The frequency and margin by which Group III displays less arousal also appears to parallel the comparison cited in Figure 4a.

Comparison of the two control conditions (Figure 4c) reveals a relatively even distribution with respect to the frequency with which one group exceeded the other. The extent to which groups differed also appears less than those cited in the previous two figures.

Despite an absence of statistical significance, Figures 4a-c tend to support the premise that N₂O had a positive effect. Subjects receiving N₂O consistently manifested lower HR than control subjects during the placement of topical anesthesia, injection, and cavity preparation across visits.

Interpretation of the impact of discontinuing the mask conditions for Visit 5 is somewhat confounding. Although N₂O subjects continued to display less arousal than their counterparts (fig. 4a and 4b) a relative increase in their mean HR was observed

Fig.3a SEQUENTIAL VISIT \overline{HR} across INTERVALS

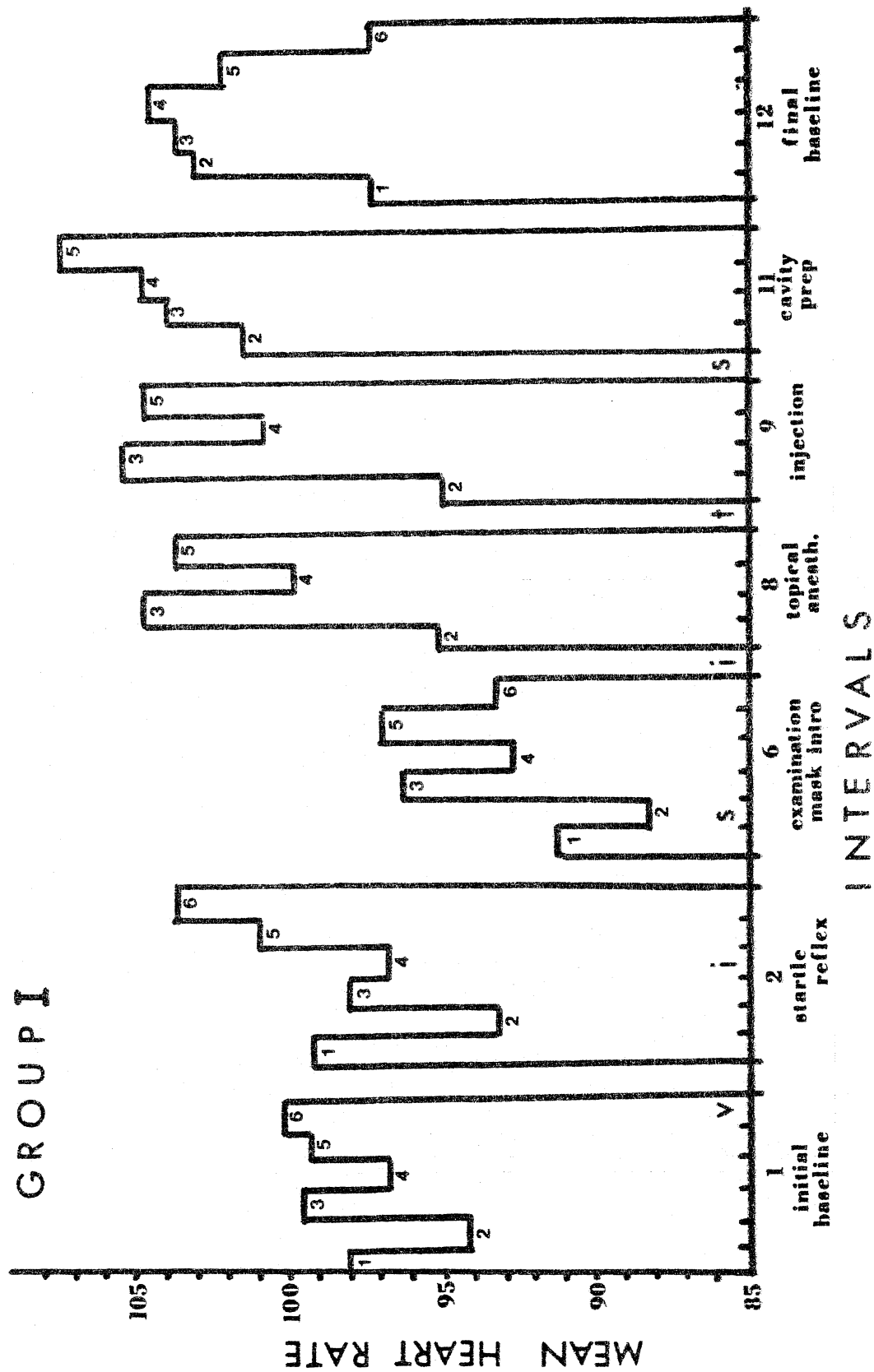


Fig. 3b SEQUENTIAL VISIT $\overline{\text{HR}}$ across INTERVALS

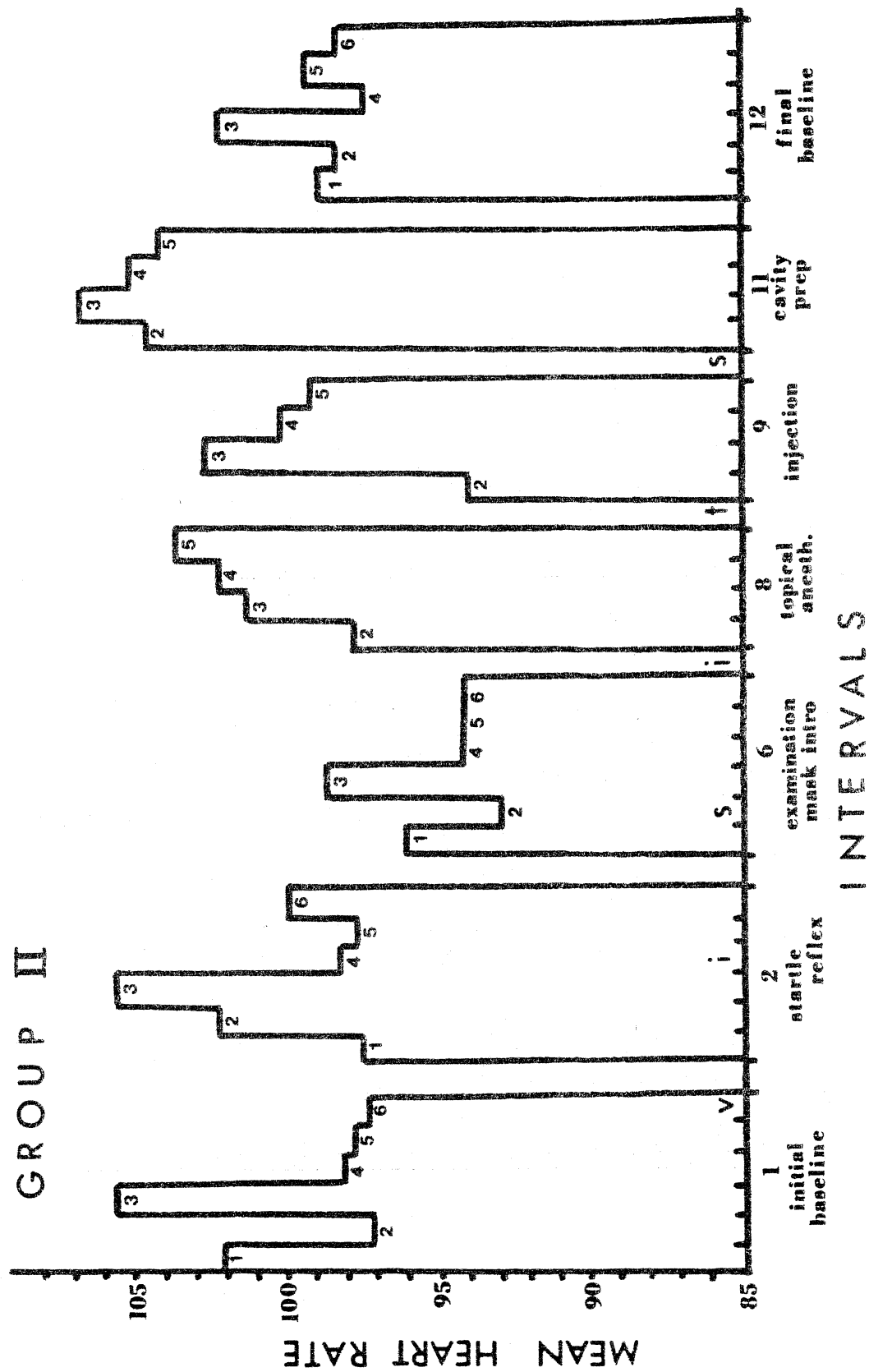
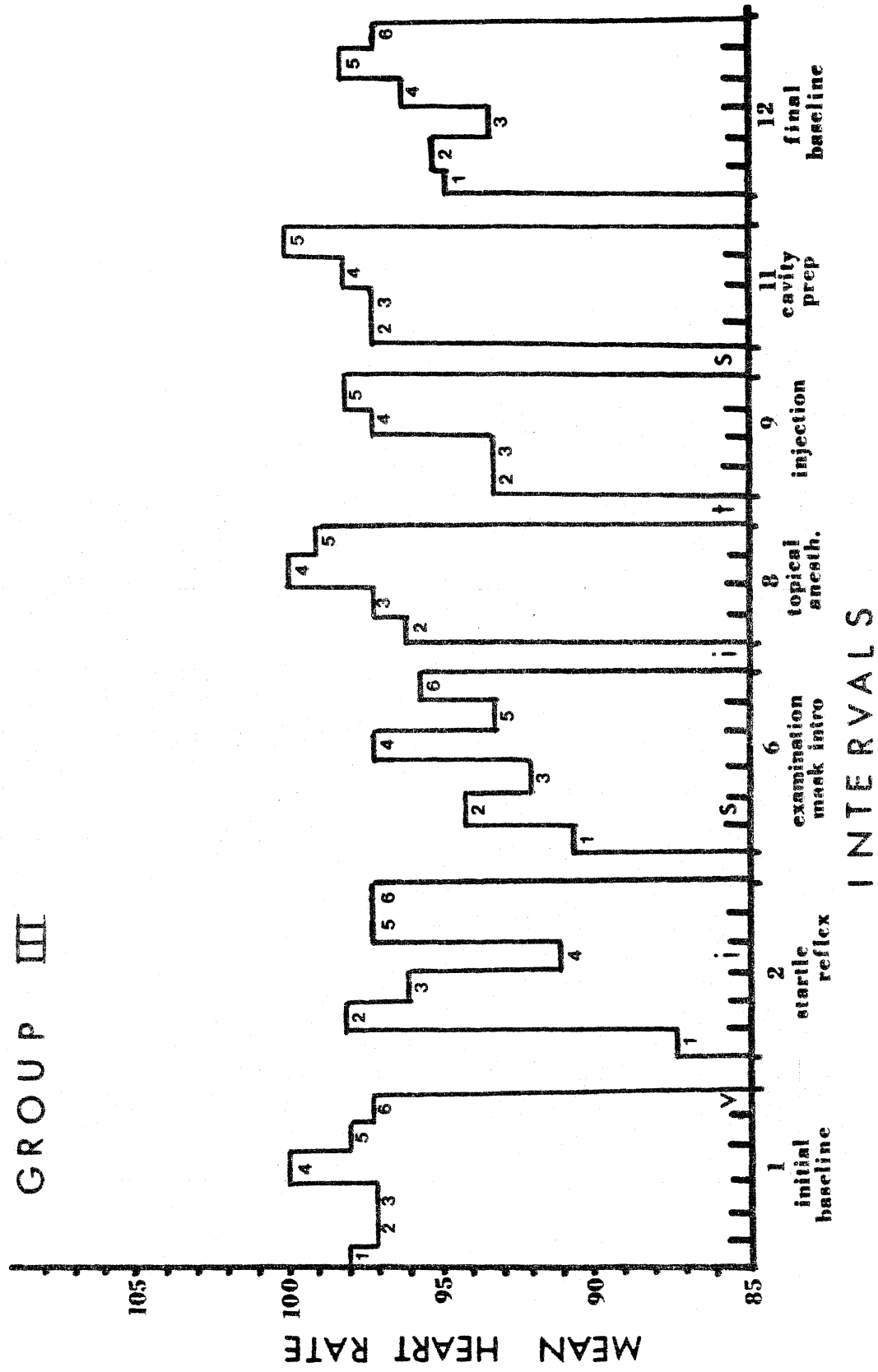


Fig.3c SEQUENTIAL VISIT $\overline{\text{HR}}$ across INTERVALS



between visits 4 and 5. Had a similar increase between visits 3 and 4 not occurred, a strong argument could be made in support of a positive short-term effect of N_2O . As a result, it is unclear whether the increase during Visit 5 is attributable to a dependence upon the N_2O to maintain lower levels of arousal, or, despite the slight increase upon withdrawal, N_2O had contributed sufficiently to the development of coping skills to sustain lower arousal. Compared to Group I (figure 4a) Group III showed a mean heart rate of 100 compared to 108 during cavity preparation. No differences were found in Table 3.

Statistically, it should not be surprising that these relative differences do not reach significance given the wide individual variation and limited sample population size. However, a more meaningful assessment can be derived by a comparison, for example, of HR during intervals 6 and 11 (figure 4a) where HR originated in the range of 95 for both groups. The dilemma, however, remains in identifying the magnitude of the difference in HR at which clinical significance can be ascertained.

Figures 4a and b show a greater difference across intervals 9 and 11 between Groups I and III during Visit 5 than II and III. Interestingly, Group II subjects displayed a reduction in mean HR when the mask conditions were removed while Group I continued to worsen. It is not clear from the data whether improvement in Group II ultimately resulted from adaptation and learning across visits or from removal of the noxious mask, or both. Since Group I continued to show even greater arousal during Visit 5, it seems likely that the delivery of O_2 alone exacerbated fearful reactions. Evidence to support a placebo effect of the mask is therefore remote.

Fig.4a SEQUENTIAL VISIT HR across INTERVALS

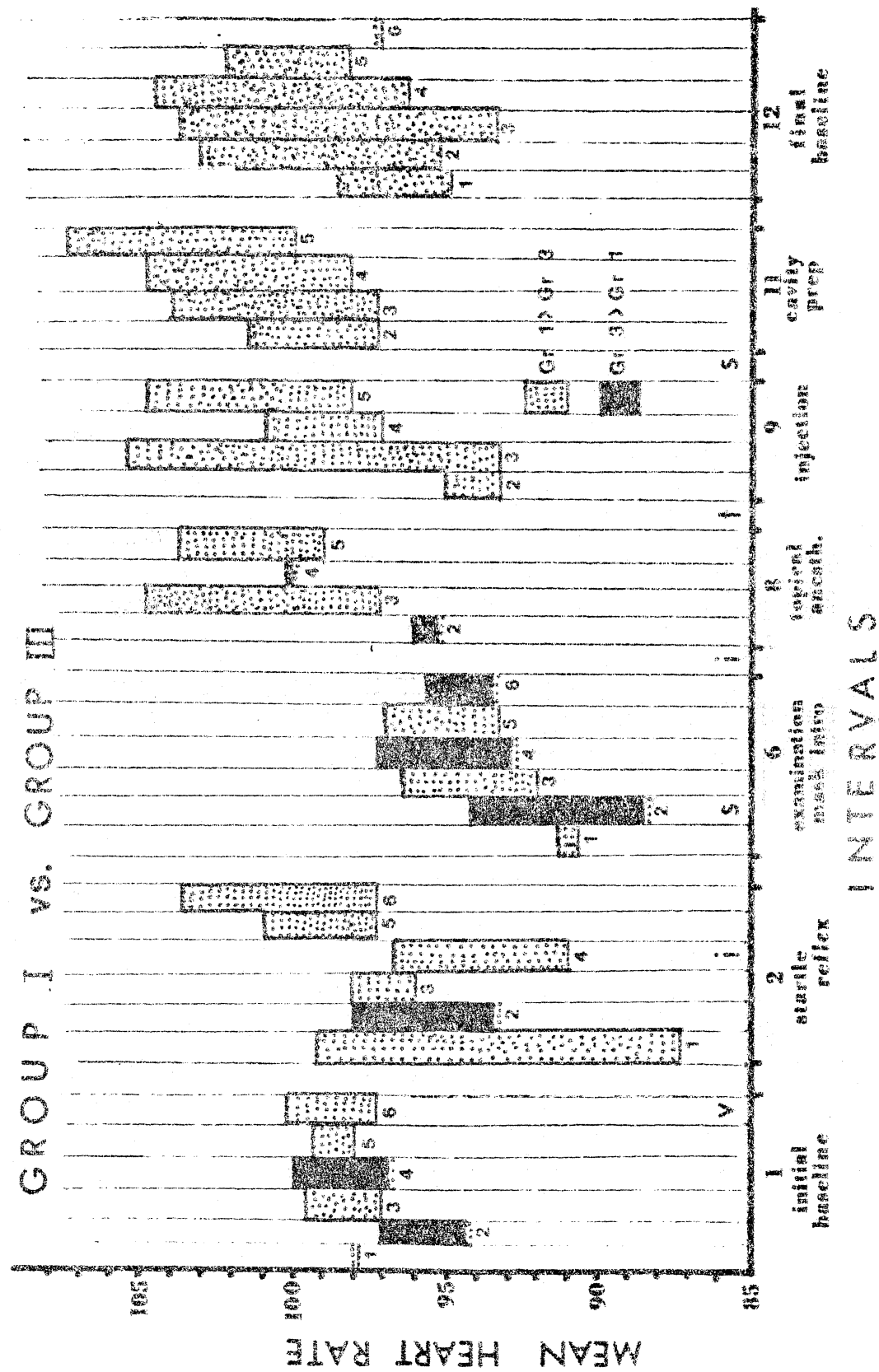


Fig. 4b SEQUENTIAL VISIT HR across INTERVALS

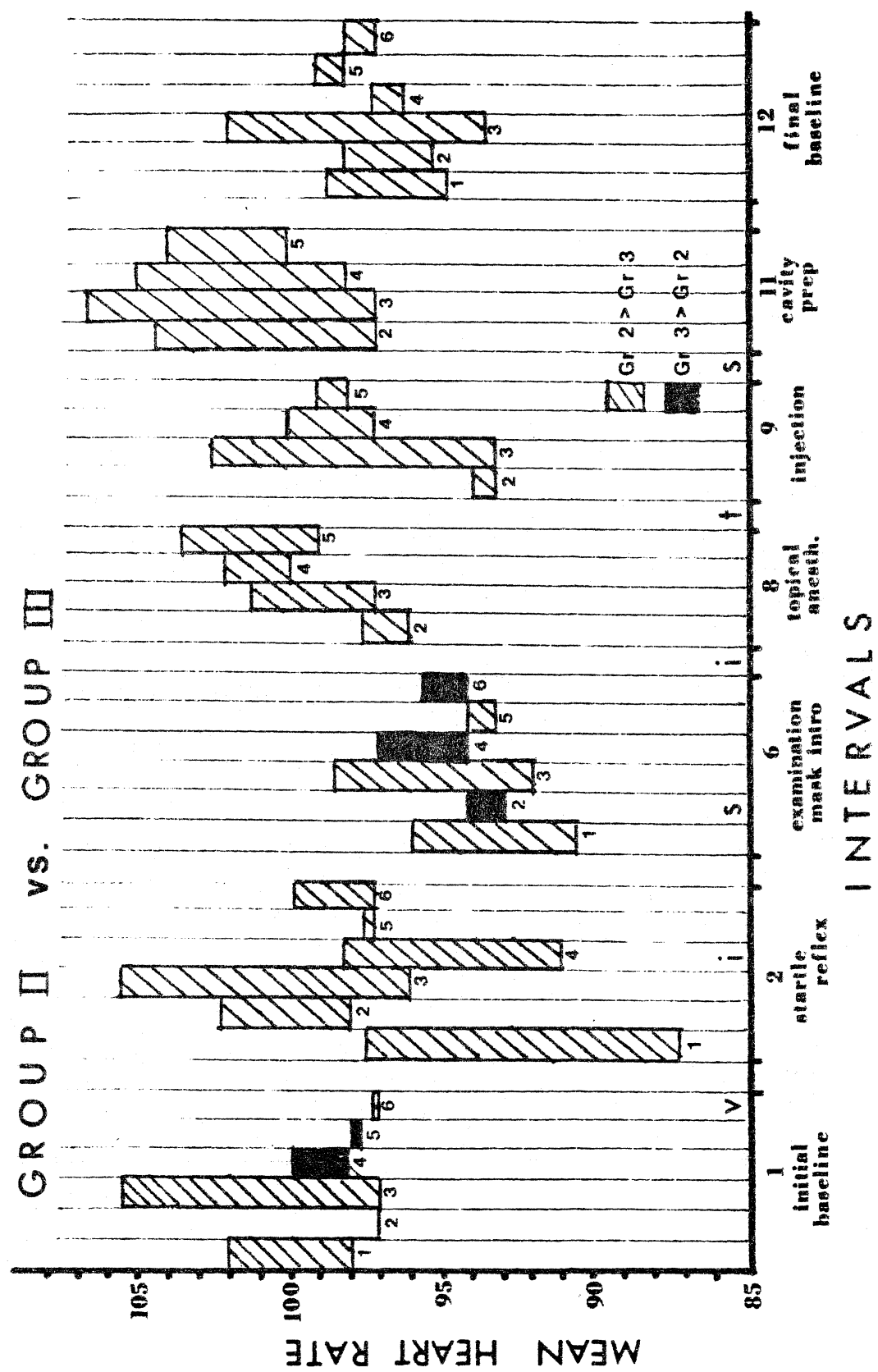
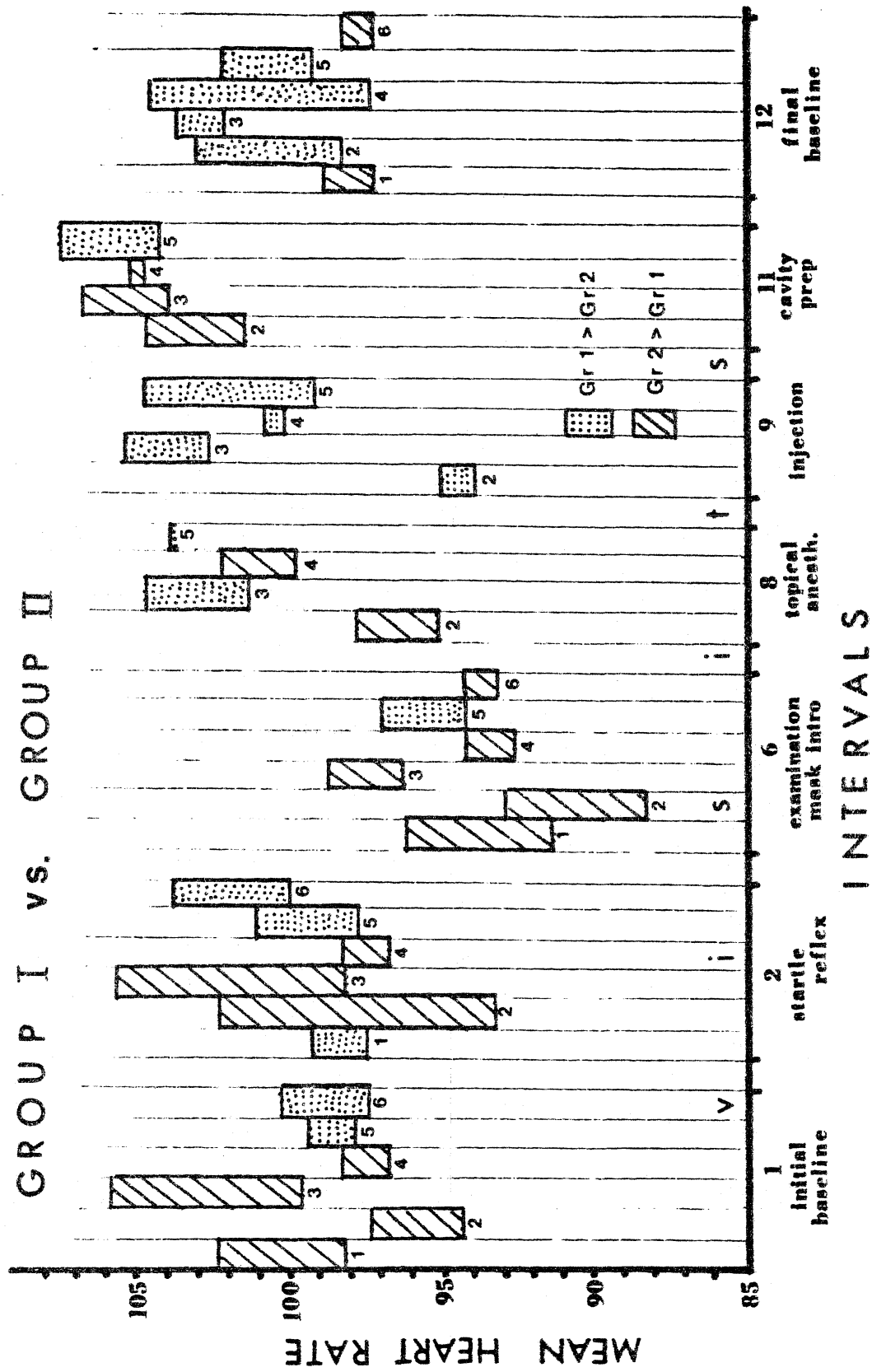


Fig.4c SEQUENTIAL VISIT \bar{HR} across INTERVALS



Assessment of the data obtained from the observational ratings is needed at this point to permit more meaningful interpretation of the variability in HR found for groups across visits and specific events.

2. Clinical Ratings of Anxiety and Behavior

As described previously, behavioral data was derived from clinical ratings of anxiety and behavior (Appendix IV) during 2 specific anxiety provoking intervals - injection of local anesthesia and cavity preparation.

a. During injection of local anesthesia

The results of the ANOVA found differences between groups at this p value. Because, however, of violations of assumptions of normality and equal variation, it was felt that further analysis would not be appropriate. Thus no multiple comparisons to identify group differences were carried out.

Table 4a Two-Way Analysis of Variance with Repeated Measures for Clinical Ratings of Anxiety and Behavior during Injection of Local Anesthesia across visits 2-5

VARIABLE	SOURCE	DF	TYPE I SS	F [∞] VALUE	PR>F
Anxiety	Group	2	0.81	9.96	0.0124*
	Visit	3	0.17	1.45	0.3184
Behavior	Group	2	0.40	3.76	0.0874
	Visit	3	0.05	0.33	0.8052

* p < .05

Figure 5a plots the cumulative anxiety and behavior scores during injections for each group across Visits 2-5. It should be noted that the plots do not reflect Group II having two more subjects and as result, the magnitude of the differences for this group are inflated. Figure 5b compensates for this discrepancy by comparing the mean group scores. Despite the inequality in group size, a similar pattern was observed with Group III manufacturing less anxiety and uncooperative behavior than Groups I and II. The highest levels of anxiety and uncooperative behavior were recorded by Group II. The greatest differences were observed during Visit 4.

Longitudinally behavior and anxiety were observed to deteriorate across the initial restorative visits before an improvement was noted for Groups I and II during the final treatment visit. Group III, on the otherhand, sustained lower anxiety ratings and more favorable behavior across visits; this finding is supportive of a beneficial immediate effect of N₂O.

As had occurred for heart rate, discontinuation of N₂O does not appear to have resulted in a substantial deterioration in Group III's cooperation. Similar, however, to the slight increase in HR observed from visit 4 to 5, a corresponding rise in anxiety and uncooperative behavior is seen for Visit 5 (figures 5a and 5b). Improvements in Groups I and II between visits 4 and 5 contribute to the explanation for why statistical difference might not be found over Visit 5. Despite improvements of Groups I and II, Group III still displayed the least anxiety; hence, a carry-over or long-term effect of N₂O cannot be discounted.

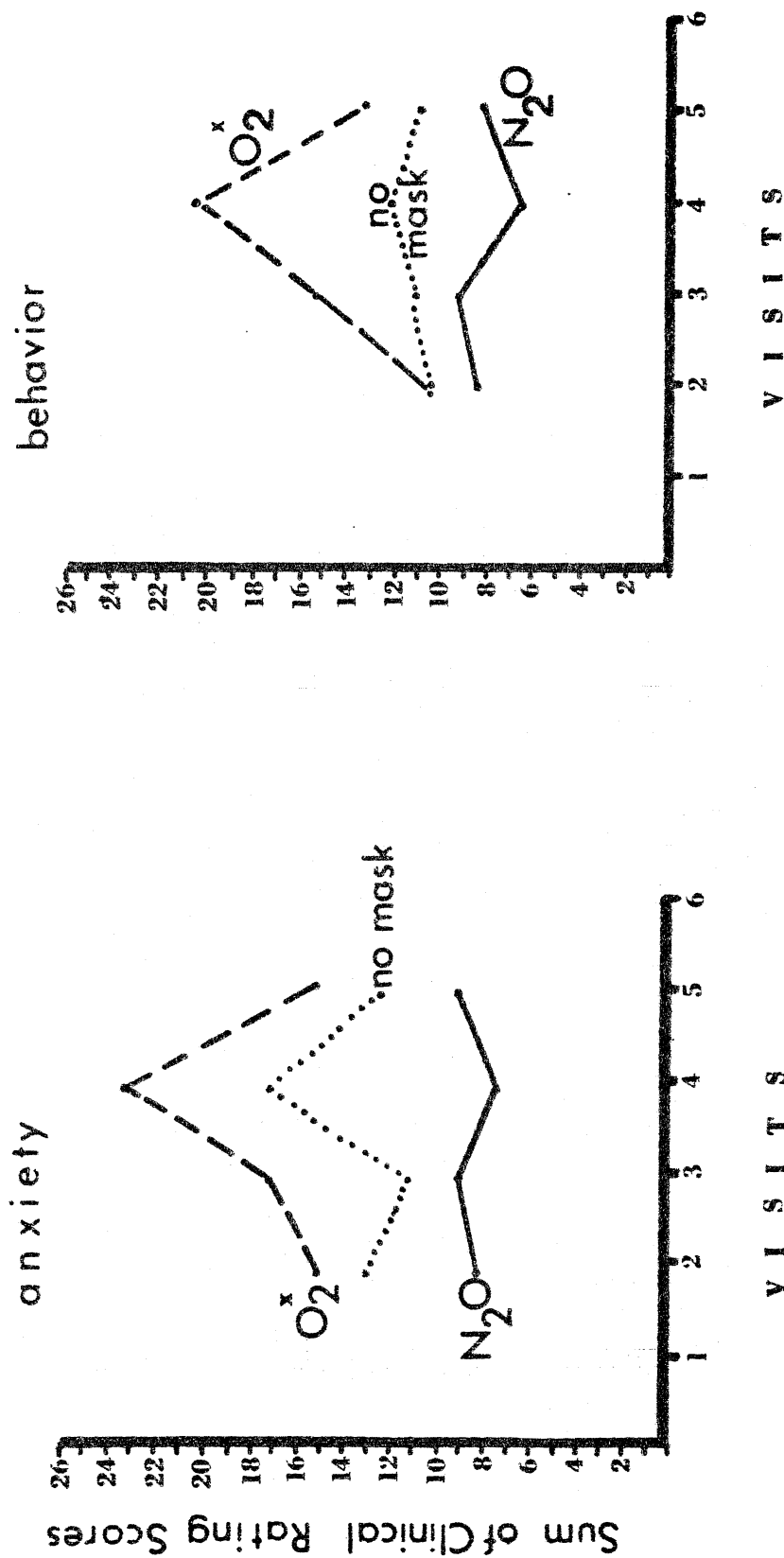


Fig. 5a GROUP TOTAL^x SCORES for CLINICAL ANX. & BEH. RATINGS during INJECTIONS

^x plots for group two: N=13

Figures 5c and 5d depict the relative distribution of anxiety and behavior scores for groups across visits. The most striking comparison relates to the percentage in which subjects from each group received "zero" ratings (no clinical sign of anxiety or uncooperative behavior). No discernible differences were apparent with respect to the numbers of subjects displaying high levels of anxiety and uncooperative behavior. A reasonable explanation to account for this finding might be that contained within each group were a small percentage of severely anxious subjects manifesting entry level characteristics sensitive only to the use of a more potent anxiety management modality. If accurate, this observation provides support for the contention that N₂O should be considered a useful adjunct only in the management of the mild to moderately apprehensive subject.

b. During Cavity Preparation

Significant group differences were found for anxiety and behavior ratings during cavity preparation (Table 4b). As described previously, analysis to include multiple comparisons to further discriminate group differences was not appropriate given an inability to assume normality and equal variation. As seen in figures 6a and 6b, differences are more likely attributable to the O₂ mask condition than between N₂O and the no mask condition.

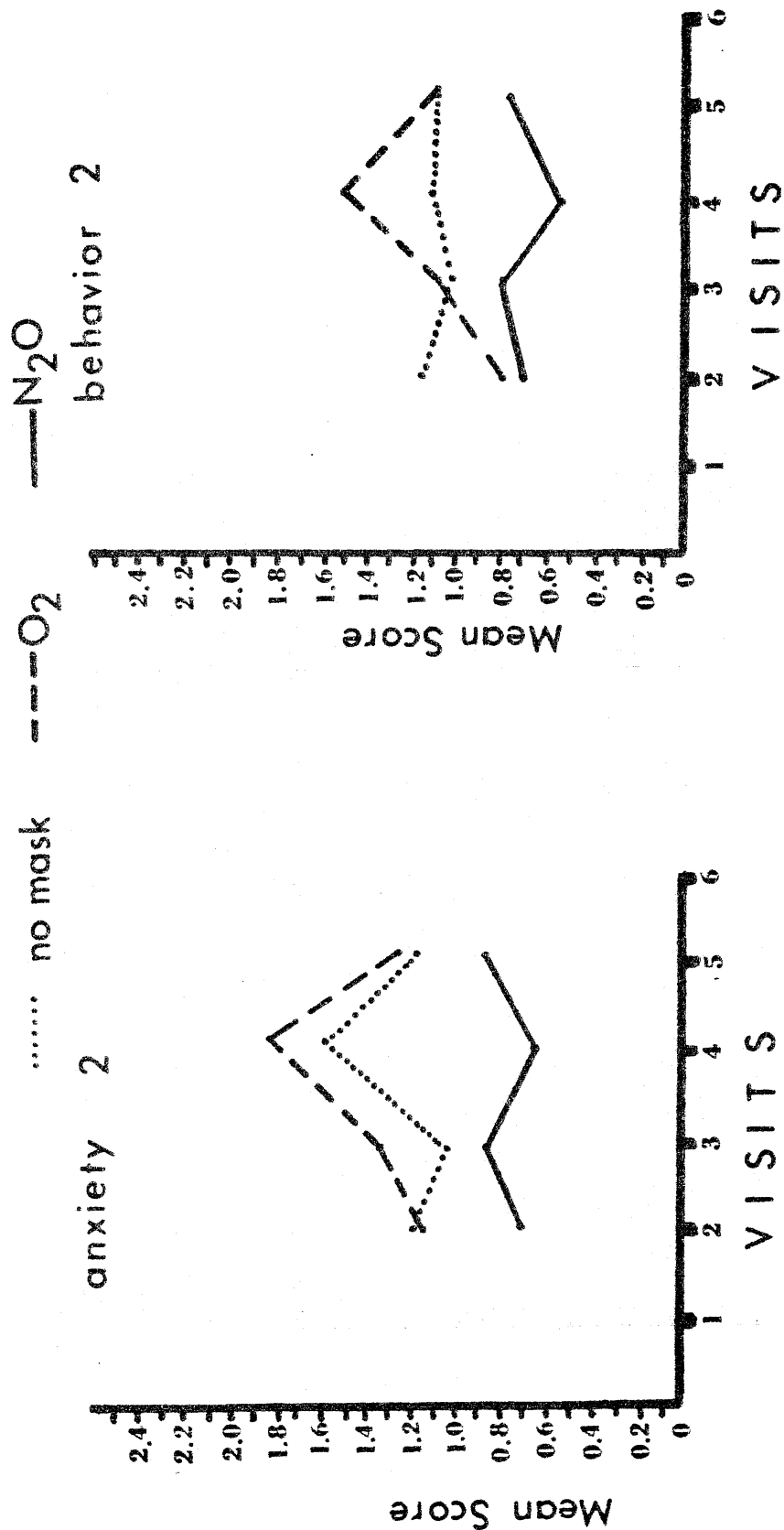


Fig. 5b MEAN ANXIETY and BEHAVIOR RATINGS during INJECTIONS

Figure 5c GROUP DISTRIBUTION of ANX^x RATING SCORES during
INJECTION of LOCAL ANESTHETIC

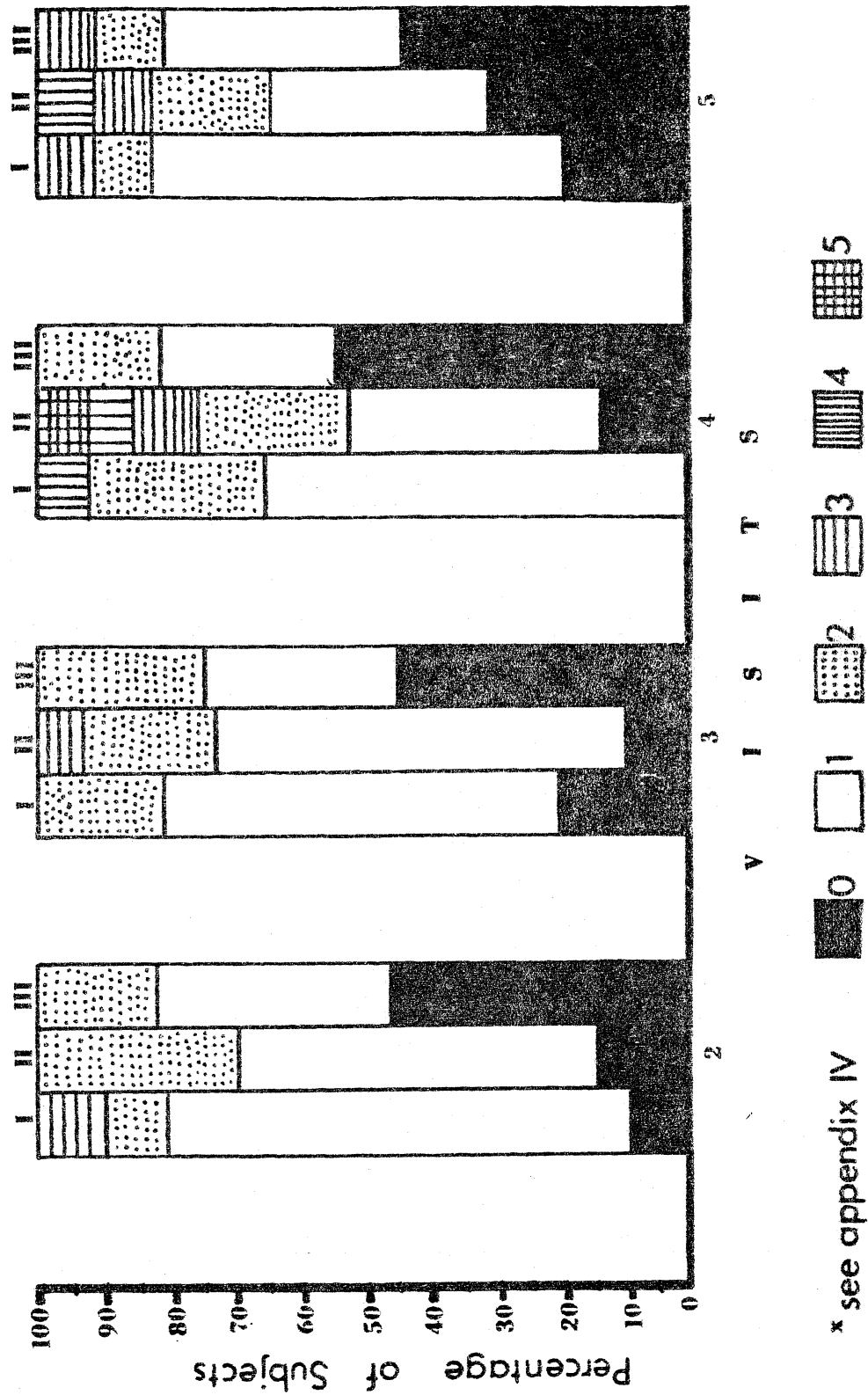


Figure 5d GROUP DISTRIBUTION of BEH.^x RATING SCORES during INJECTION

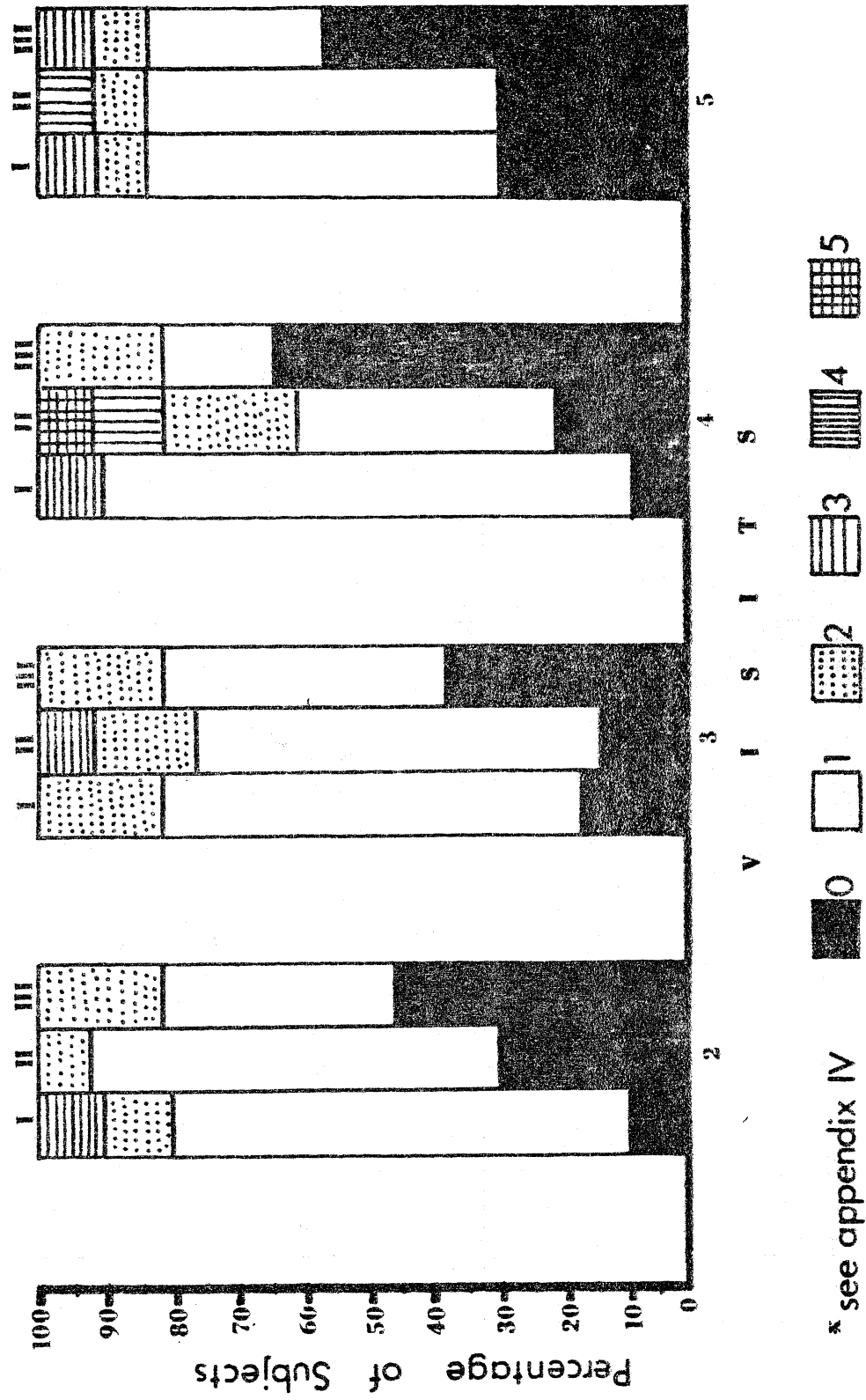


Table 4b Repeated Measures Analysis of Variance for Clinical
Ratings of Anxiety and Behavior during Cavity
Preparation across Visits 2-5

VARIABLE	SOURCE	DF	TYPE I SS	F VALUE	PR>F
Anxiety	Group	2	0.84	9.62	0.0134*
	Visit	3	0.17	1.34	0.3457
Behavior	Group	2	0.83	7.84	0.0212
	Visit	3	0.09	0.61	0.6344

* p < .05

+ p < .01

Figures 6a-6d, addressing the same parameters as Figures 5a-5d, focus on responses during interval 11 - cavity preparation.

As in Figure 5a, Group II's larger sample size is overlooked in Figure 6a. Both the cumulative scores (Figure 6a) and the mean anxiety and behavior scores (Figure 6b) during cavity preparation parallel the group responses manifested during injection of local anesthesia. N₂O subjects displayed the lowest ratings across visits 3, 4, and 5. O₂ subjects again displayed the highest anxiety levels and most uncooperative behavior.

As predicted, anxiety and behavior of control subjects was observed to deteriorate progressively across the initial 2 restorative treatment visits. Conversely, N₂O subjects manifested an improvement through Visit 4; discontinuation of N₂O on Visit 5 again resulted in a minimal increase in anxiety and behavior scores. Despite the turnabout, Group III maintained better behavior and less anxiety than its counterparts.

Figures 6c and 6d support the conclusion that Group III<I<II with respect to the display of anxiety and uncooperative behavior.

Effect of N₂O on the need for Physical Restraint

Figure 7 illustrates the frequency for which either a soft or hard restraint technique was utilized to accomplish treatment. Soft restraint was defined as including brief and non-repeating episodes of hand-over-mouth, occasional and mild hand, arm or head restraint. Hard restraint included repeated episodes of hand-over-mouth, or a need for continuous restraint for interfering and uncontrollable head, trunk or extremity movement.

No group differences were observed with respect to the frequency with which either soft or hard forms of restraint were required. The need for aversive techniques in the case of Group III subjects supports the premise that N₂O is likely too be of limited value in the management of severe acute situational anxiety.

Self-Report Measures

The sequential pre-treatment responses to the picture selection task and human figure drawing are shown in Figure 8.

Although N₂O subjects showed scores indicative of less anxiety, the differences between groups are obviously negligible for the Picture Selection Task.

With respect to the HFD task, N₂O subjects were the most apprehensive. This assessment is certainly in contradiction to

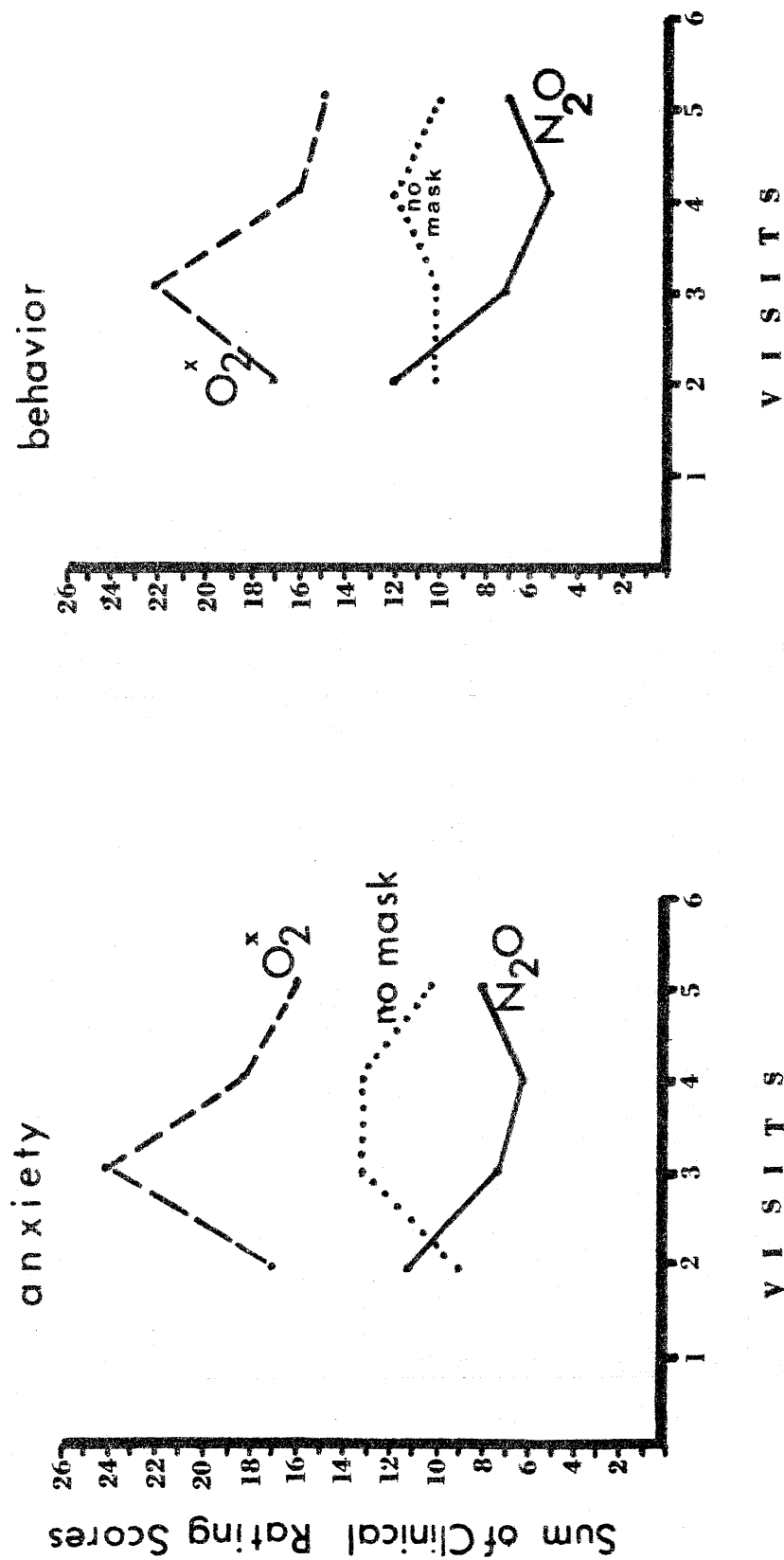


Fig. 6a GROUP TOTAL^x SCORES for CLINICAL ANX. & BEH. RATINGS
during CAVITY PREPARATION
^x plots for group two: N=13

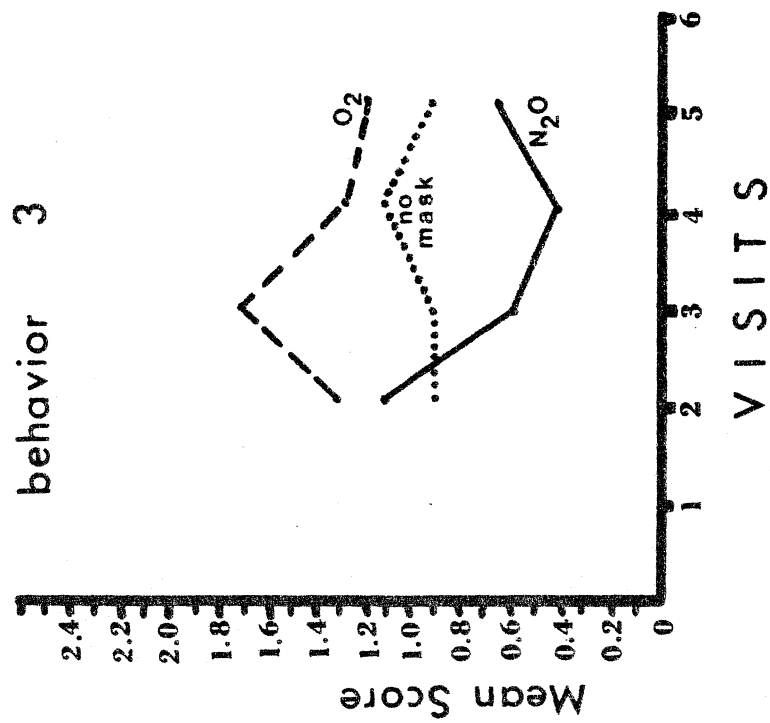
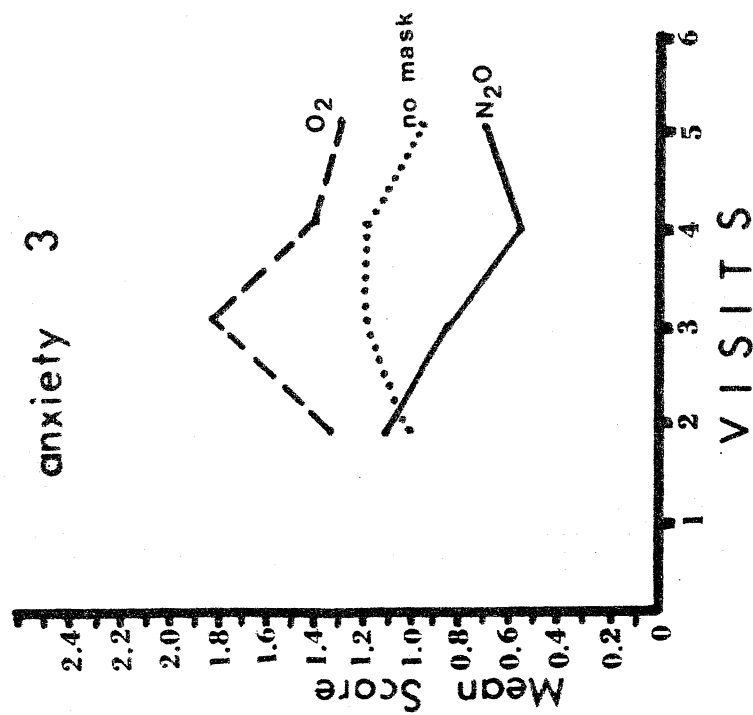


Fig 6b MEAN ANXIETY and BEHAVIOR RATINGS during
CAVITY PREPARATION

Figure 6c GROUP DISTRIBUTION of ANX.* RATING SCORES during CAVITY PREPARATION

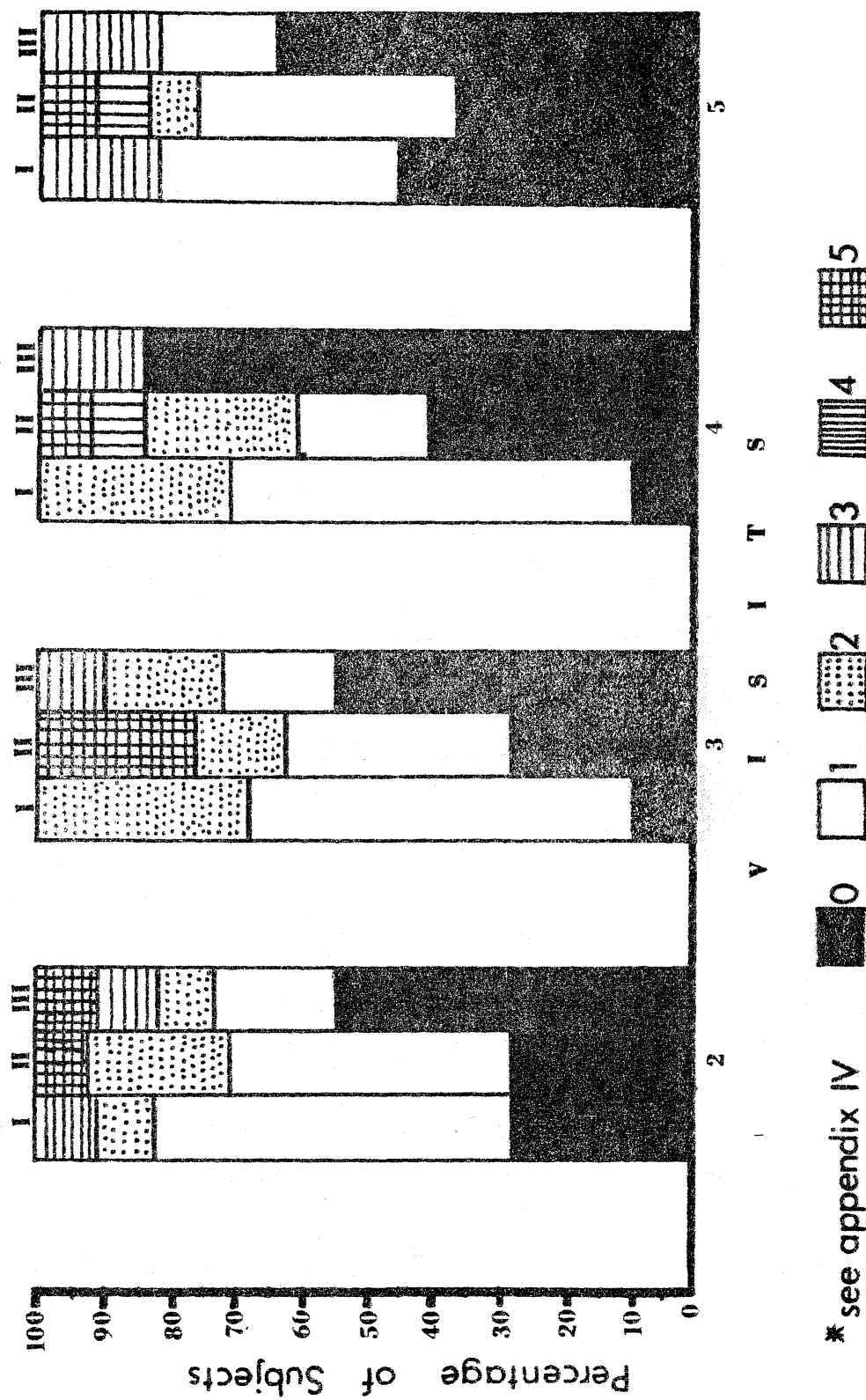
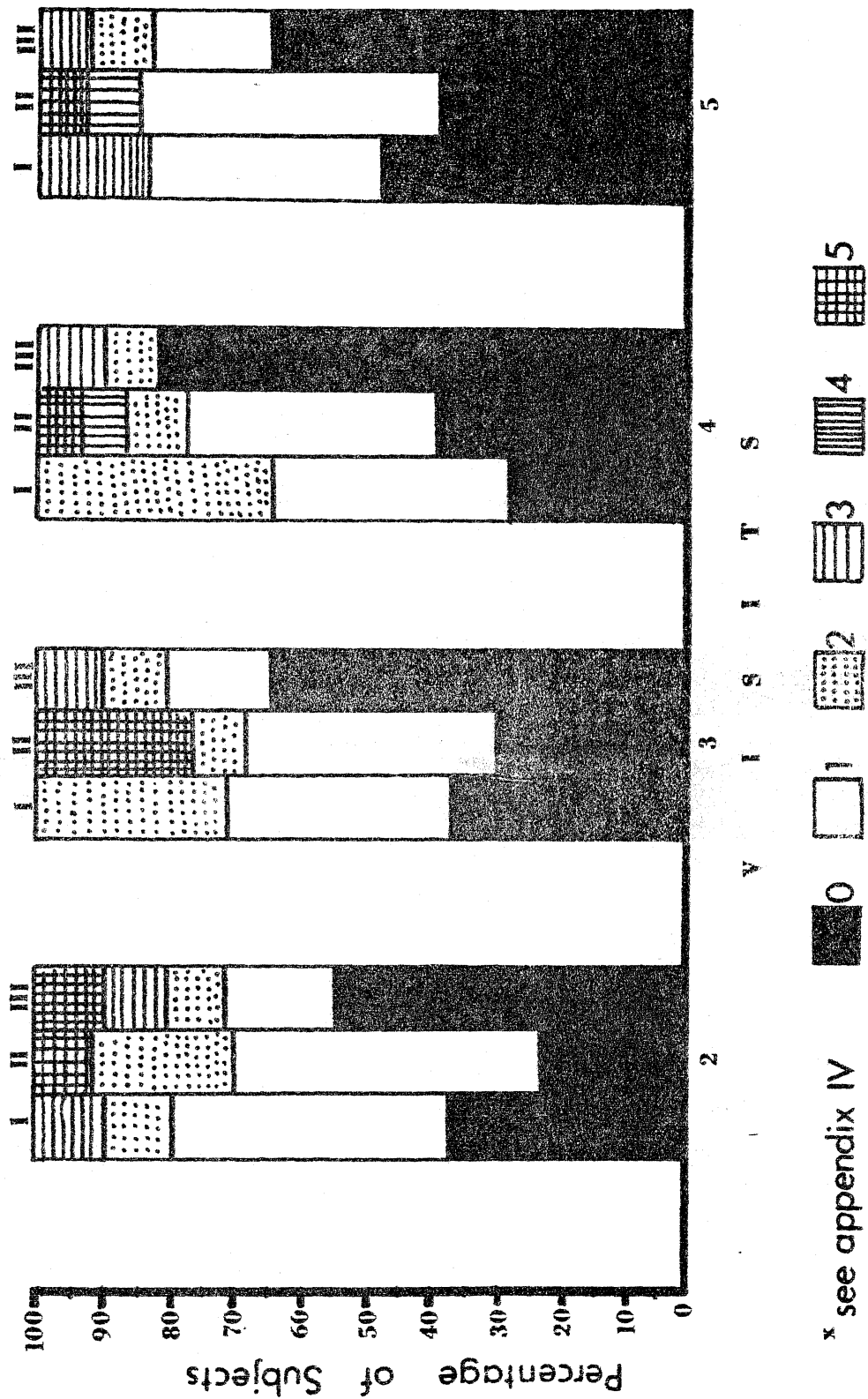
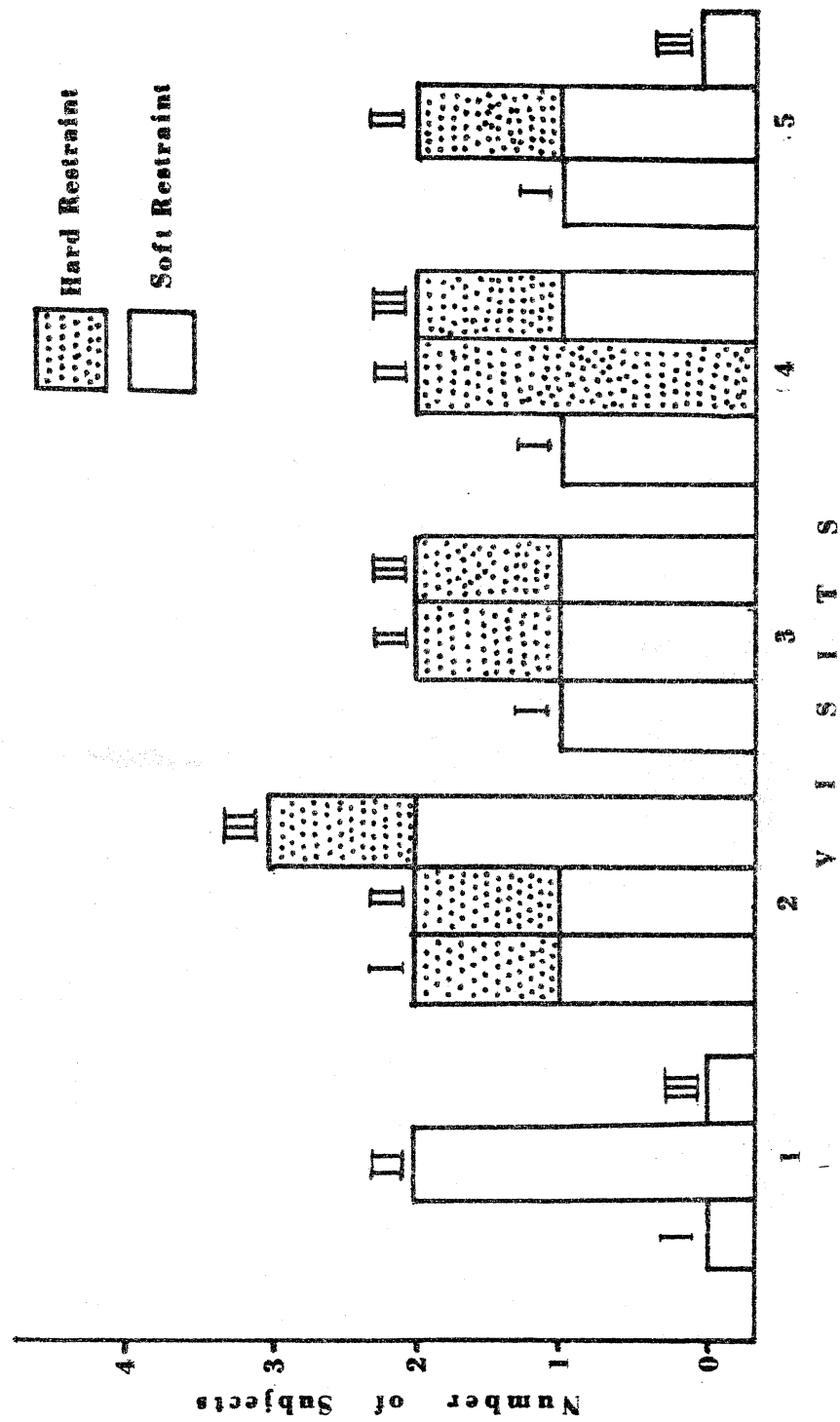


Figure 6d GROUP DISTRIBUTION of BEH^x RATING SCORES during
CAVITY PREP

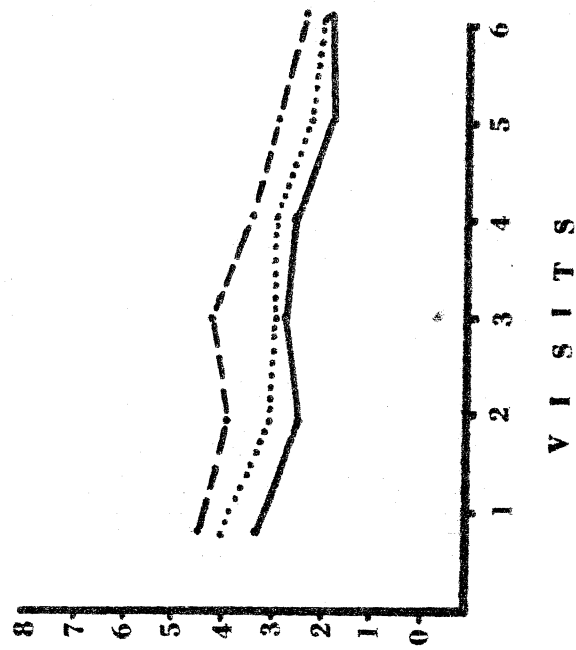


^x see appendix IV

Fig. 7 FREQUENCY of USE of RESTRAINT



Picture Selection



Human Figure Drawing

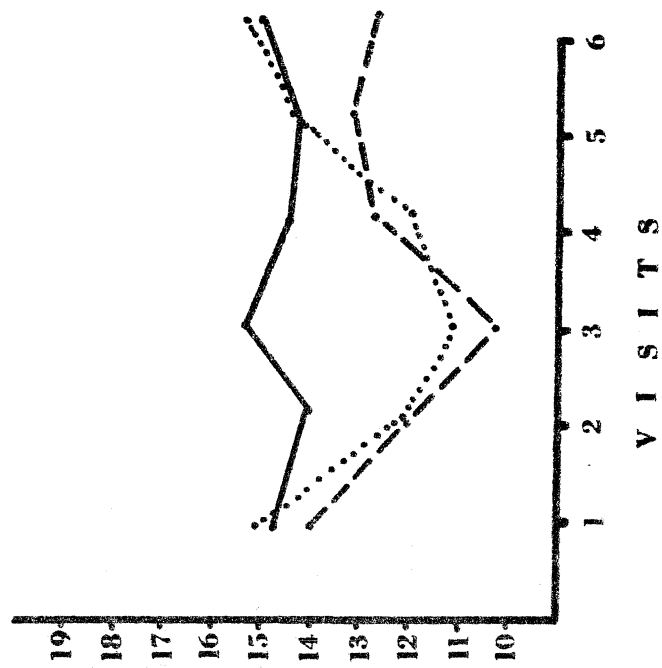


Fig. 8 GROUP MEAN SELF-REPORT SCORES

interpretations of the HR and observational data. If this test were to be considered valid in the context of this study, only one explanation could be offered to account for the results. Since this represented a pre-treatment projection which suggests that Group III subjects were the most anxious in anticipation of upcoming events, then N₂O was extraordinarily effective in helping subjects to overcome their fear. This oversimplification and analysis does appear highly unlikely. The implications and usefulness of these measures are addressed in the discussion section.

3. Correlations between Heart Rate and the Observational Ratings

Figures 9a-f illustrate the sequential physiologic and observational ratings for individual subjects during injections and cavity preparation. These figures graphically depict the extremely wide variability within and between subjects across these dependent measures. Even superficial analysis of the individual data provides ample justification for the emphasis placed upon the variability observed, the impact on finding statistical significance, and the importance of the descriptive analyses.

E. DISCUSSION

1. General

An orientation which stresses the role of cognitive, adaptive, and learning processes in anxiety and anxiety management supports the plausibility of N₂O's effectiveness with the apprehensive child. Among the psychological effects attributed to N₂O are the induction of a relaxed state accompanied by a sense of safety and well-being and a reduction of the aversive quality of stimuli. If nitrous produced such effects in the apprehensive child, it should function to reduce the child's emotionality in the novel dental situation.

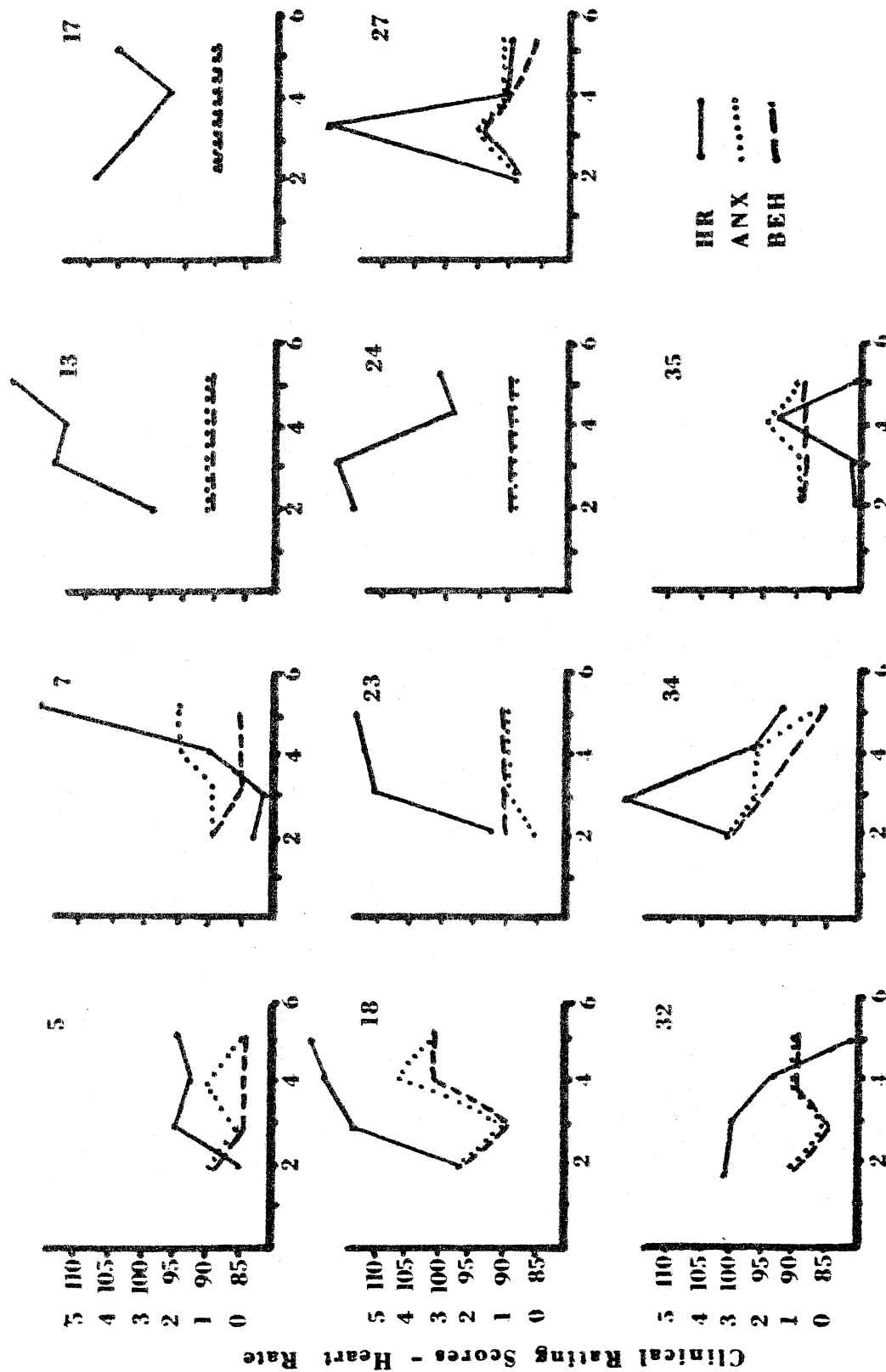


Fig. 9a INDIVIDUAL (Group I) DATA across VISITS during INJECTIONS

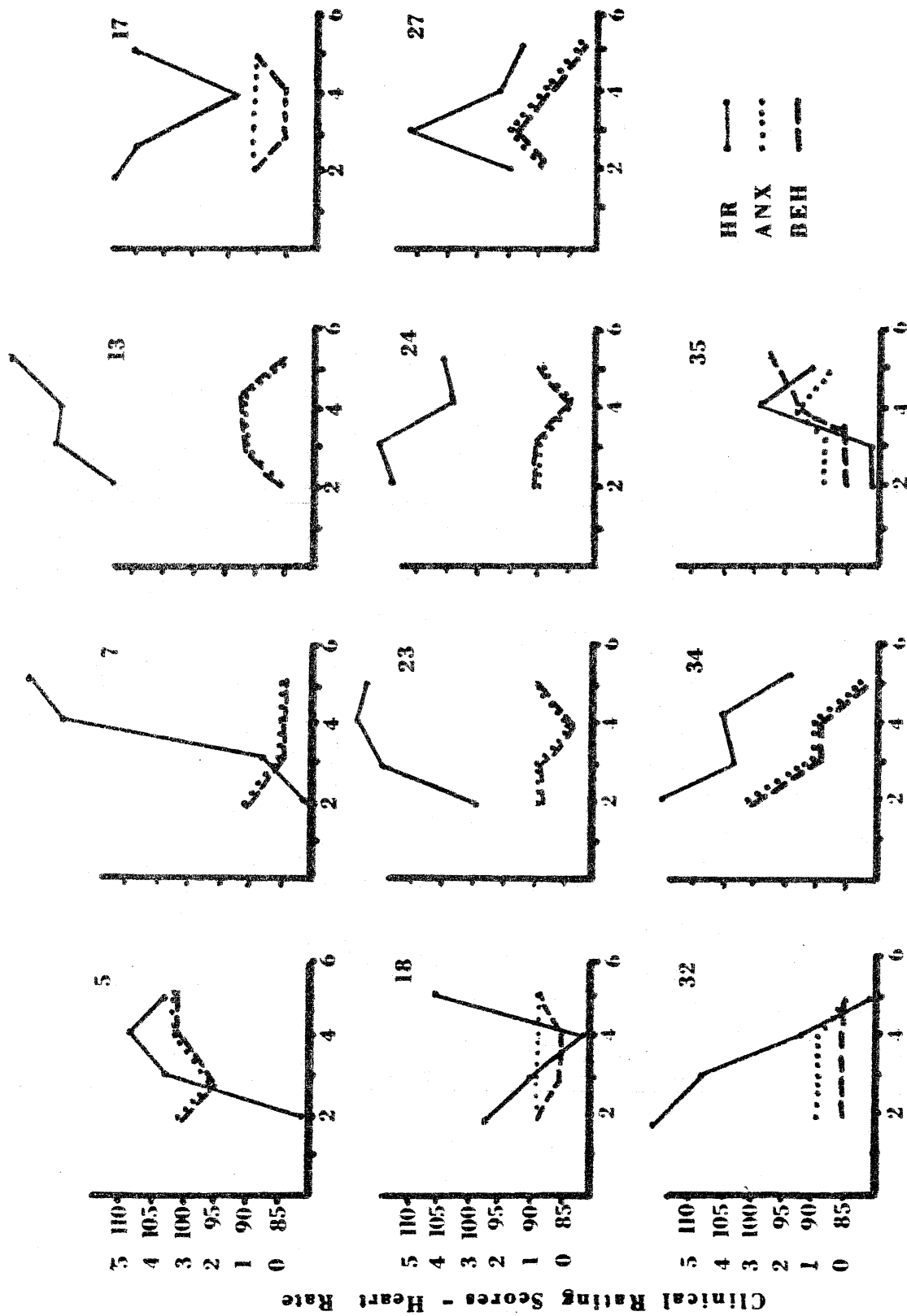


Fig. 9b INDIVIDUAL (Group I) DATA across VISITS during CAV. PREPAR.

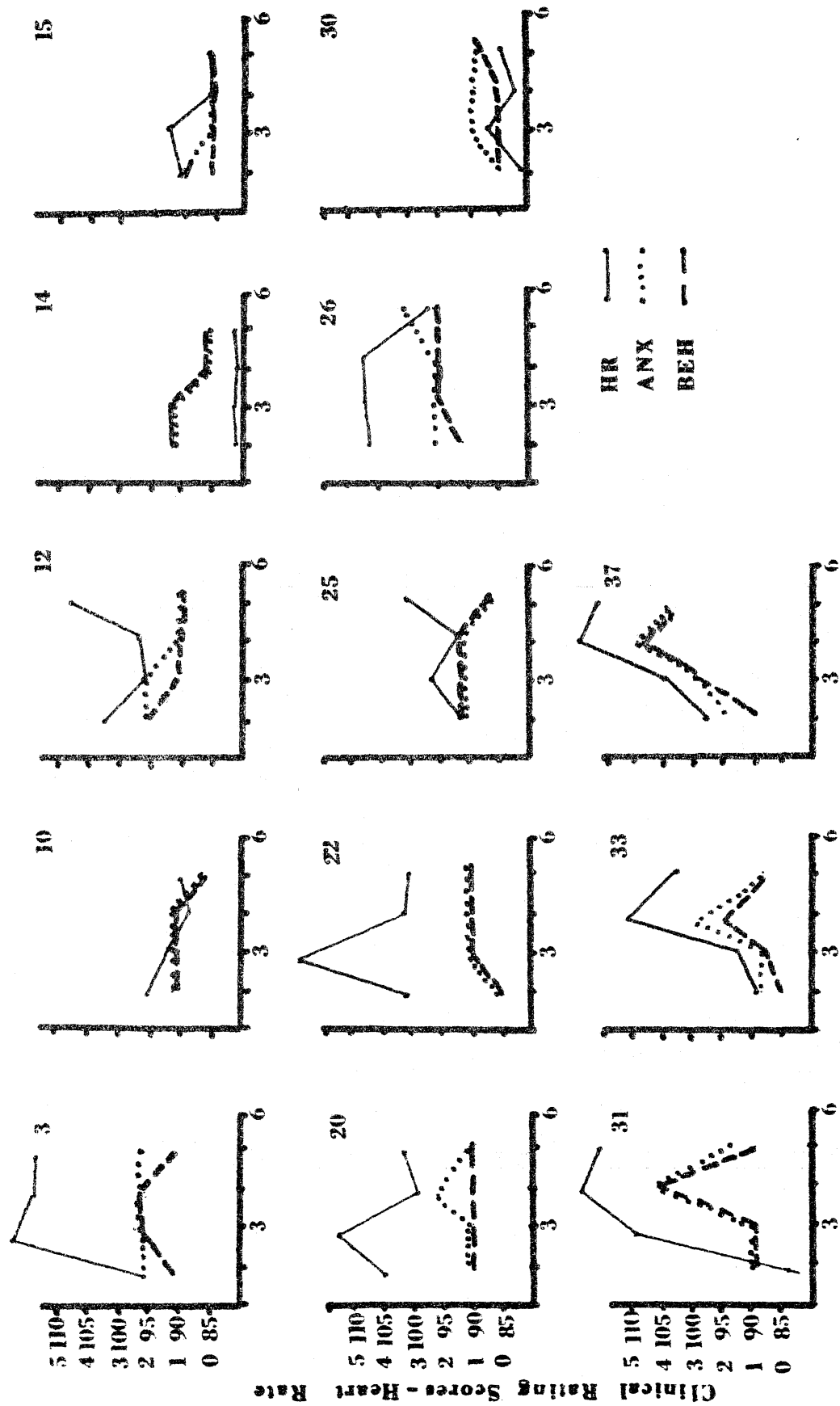


Fig. 9c INDIVIDUAL'S DATA across VISITS during INJECTION (GroupII)

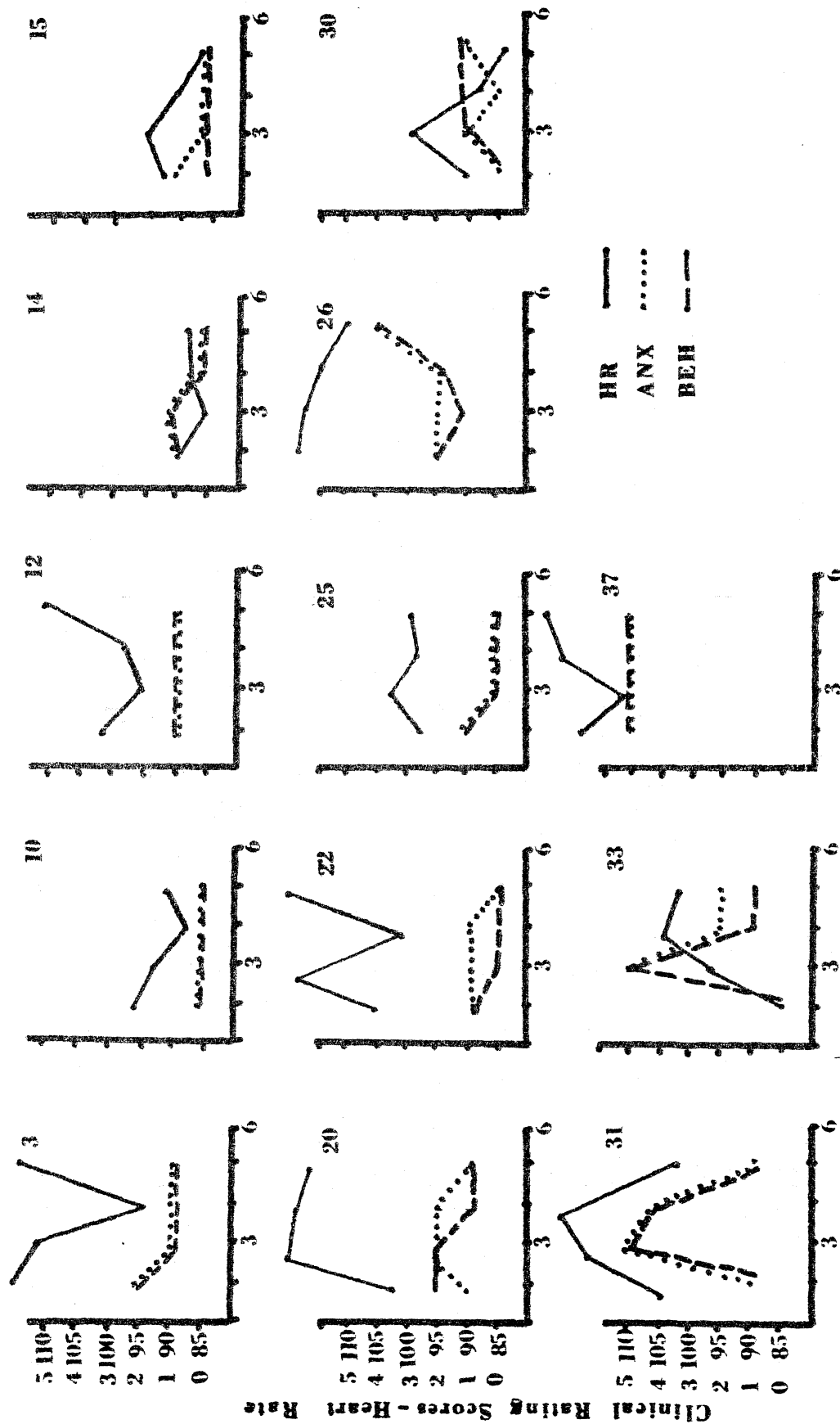


Fig. 9d INDIVIDUAL'S DATA across VISITS during CAV. PREPAR. (Group II)

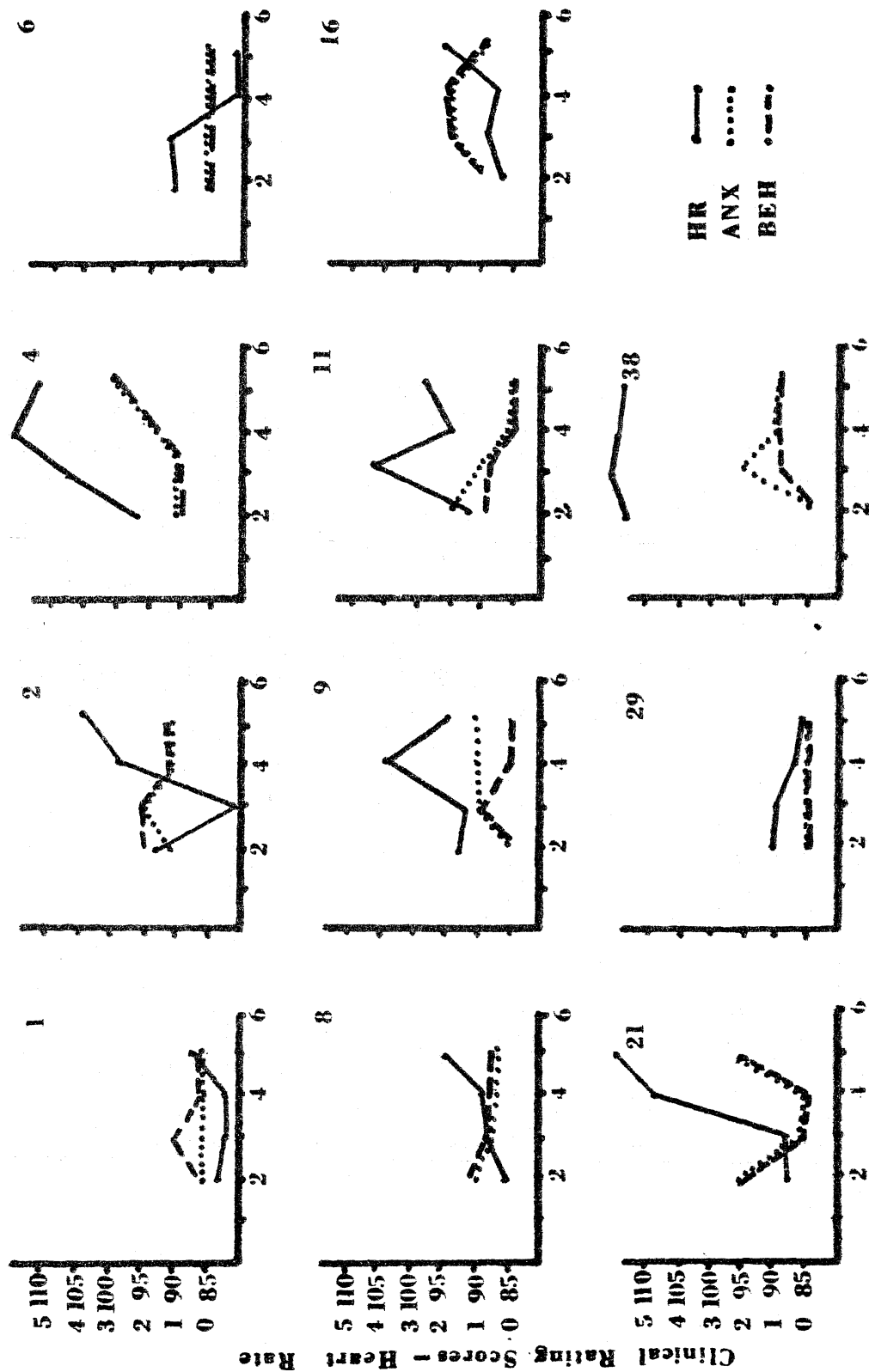


Fig.9e INDIVIDUAL (Group III) DATA across VISITS during INJECTION

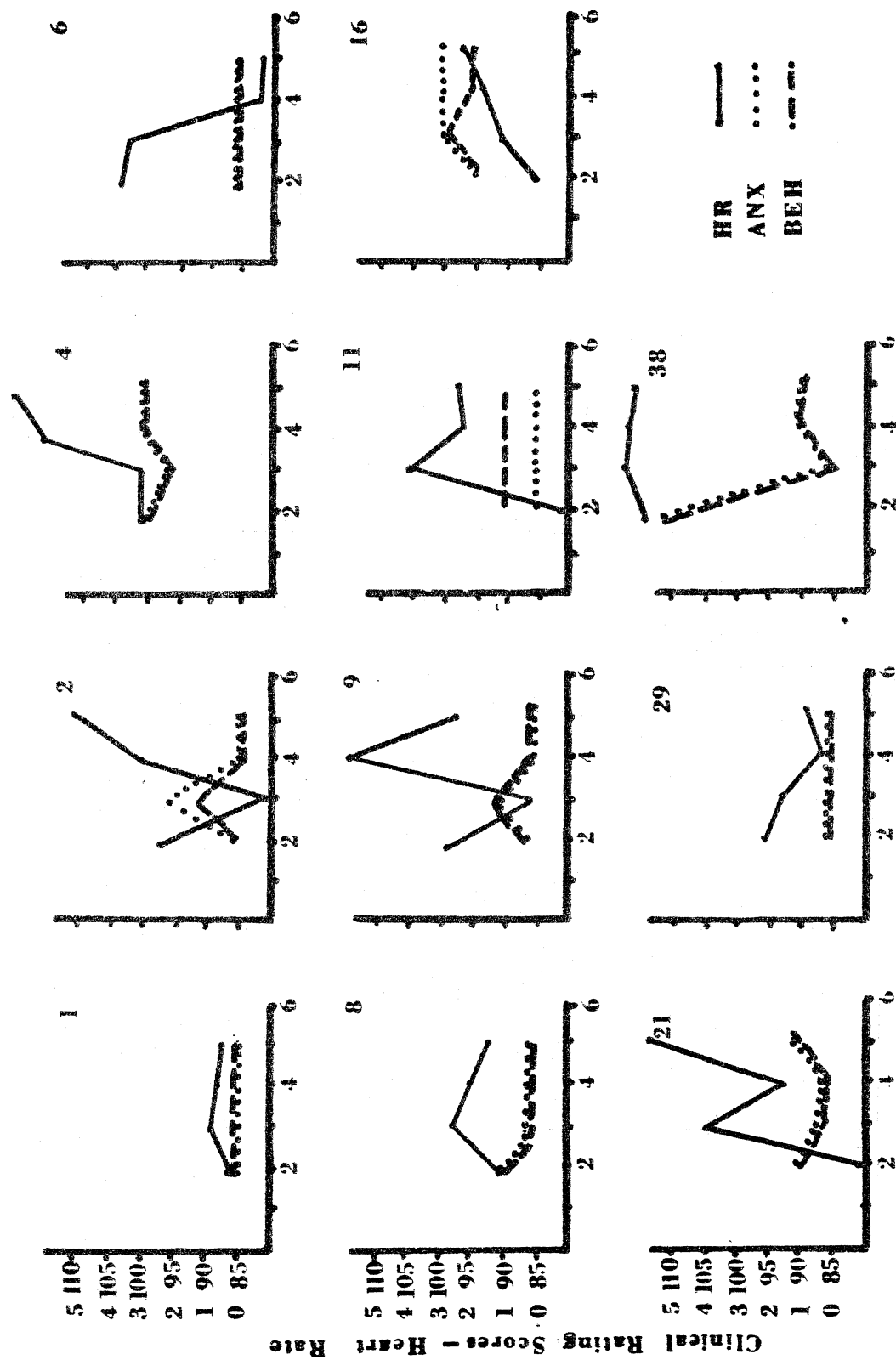
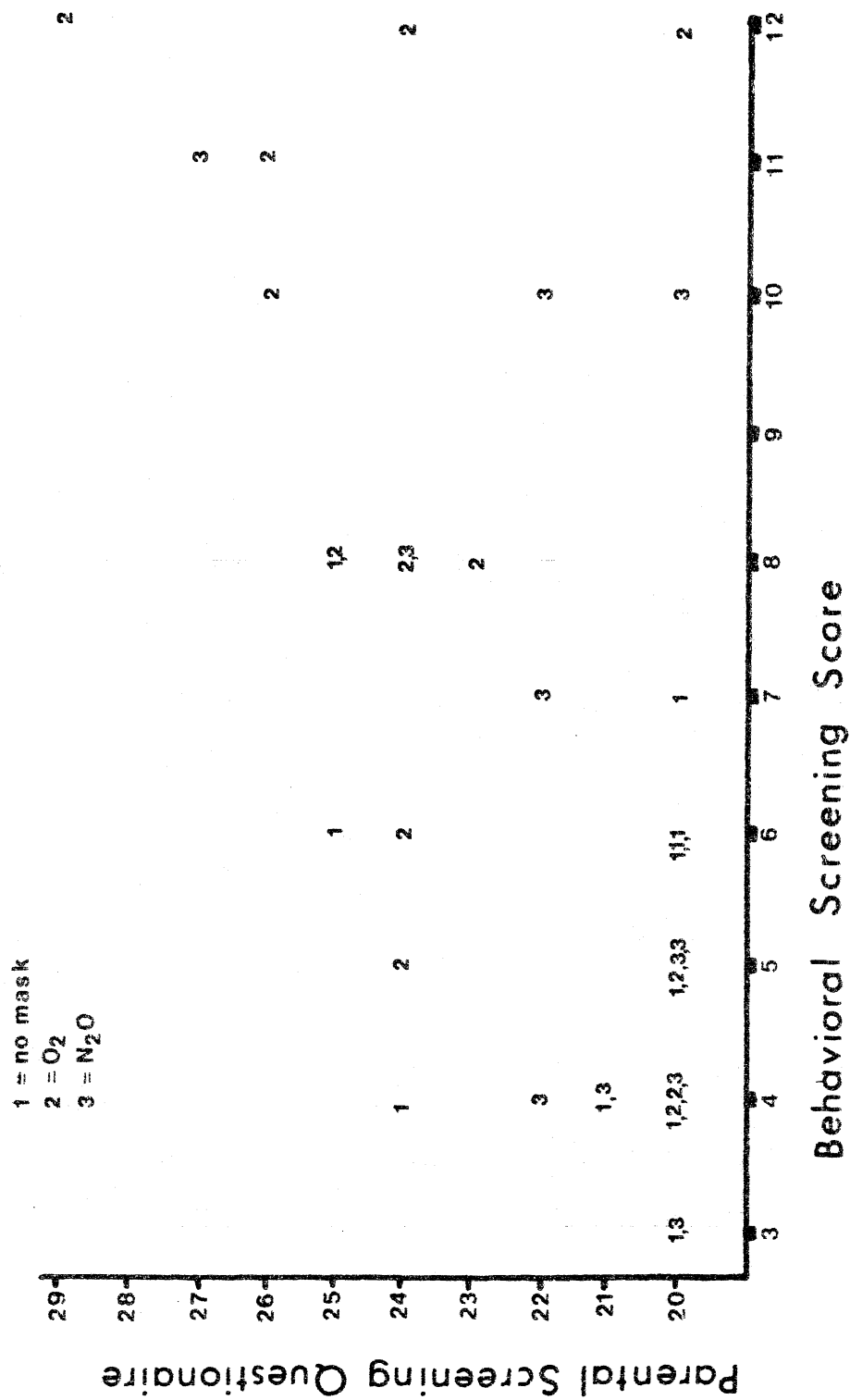


Fig. 9f INDIVIDUAL (Group III) DATA across VISITS during CAV. PREP.

Fig.10 GROUP SCREENING SCORES



Consequently, it should decrease his/her excessive vigilance, prevent distorted perception of potentially stressful stimuli, and facilitate recognition of positive aspects of the dental situation. Since the child can learn and retain new information under nitrous analgesia, conditioning processes which facilitate coping and adaptation should occur. As the child is exposed to dental stimuli in the context of an emotionally relaxed and subjectively pleasant state, positive associations toward dental care may accrue through classical conditioning. This naturalistic process would tap elements of the "desensitization" paradigm, in which the subject is trained to pair a relaxed state with anxiety-provoking stimuli. Elements of operant conditioning would also be expected to occur. If the child behaves more cooperatively under nitrous analgesia, he/she would be reinforced by the dentist for this cooperative behavior. Furthermore, the child's developing coping skills would prove self-reinforcing, since the child would experience a sense of success in coping with a stressful situation. Thus, the acquisition of adaptive coping skills should be facilitated.

It was hypothesized that nitrous oxide administration would reduce the child's dental anxiety without disrupting the learning process which occurs across sequential dental visits. It was predicted that nitrous oxide exposure would facilitate behavior management of the anxious child, reduce the child's fearfulness, and accelerate his/her adaptation to dental stress. As coping skills developed, it should be possible to discontinue nitrous oxide administration while maintaining the patient's improved attitude toward treatment.

Throughout the course of the study, several issues have emerged which have bearing upon the ability to adequately address the specific aims. Discussion will now focus on those issues most critical to this project and future N₂O studies.

2. Effect of N₂O on the frequency and degree of restraint required.

The persistence of disruptive and interfering behavior poses considerable challenge to pedodontists. The failure of verbal communication attempts to overcome resistive and non-compliant behavior can necessitate utilization of an aversive technique in the form of physical restraint. Only after exhaustive verbal efforts to manage uncontrollable, refractory, and potentially dangerous behavior were unsuccessful, mild physical restraint techniques were applied. The extent and duration of the restraint method employed was limited to the relative degree to which accomplishment of treatment was impeded. Hand-over-mouth was used for the child out of contact with reality, unable to listen or respond to verbal communication. Physical restraint of head, trunk and extremity movement was reserved solely to prevent injury to the child and dental personnel and when necessary to permit treatment objectives to be met.

It was expected that the frequency and degree to which coercive control techniques were required would be substantially less for N₂O subjects. Although certainly not to be construed as a sensitive indicator, the data nevertheless does not reflect such an effect.

The frequency for which mild and more severe forms of physical restraint was employed did not vary between groups across visits. The least number of episodes necessitating the severe form occurred with Group I. (See Figure 7). The most frequent occurrence of either form of restraint occurred with the O₂ subjects. In this regard, no placebo effect was observed. It was not surprising to see an exacerbation of anxiety under conditions where subjects were misled to believe that breathing through the mask would result in greater relaxation. Although initially hopeful in this regard, upon realization of the fact that their fears were not being resolved, ensuing mistrust and deterioration of cooperation would be understandable.

A finding suggestive of a positive longer-term and residual N₂O effect would result from a decrease in the use of restraint during and across visits. Based upon the relative frequency with which a few subjects from each group required restraint, this conclusion is inappropriate.

More accurately reflected is the limited potency of N₂O to overcome more severe apprehension. It was therefore not surprising that despite indications of a beneficial effect of N₂O, a few subjects were not favorably affected by its use.

3. Effect of varying concentrations of N₂O

As described in the inhalant delivery protocol, the concentrations of N₂O varied both within and between subjects across visits 2, 3, and 4. Analysis of directional fluctuation in

concentrations (either higher or lower) of N₂O needed to maintain or improve behavior over time would be more meaningful had significant group differences been found for HR data.

If N₂O reduced fear and facilitated the acquisition of coping skills compared to control subjects, one might expect lowered concentrations of N₂O would be needed to maintain cooperative behavior as experience accumulated. This finding would support a positive drug effect both on an immediate as well as long-term basis.

Another explanation to account for subjects needing less drug on subsequent visits would be that subjects were not as anxious as the screening procedures suggested. Initial anxious behavior sensitive to standard verbal communication and behavior management strategies early in the sequence of visits would have confounding effect. It is also conceivable that, in some situations, greater or lesser concentrations than needed may have been given without perceptible changes in behavior. One criteria for increasing levels of N₂O was failure to achieve improvement in patient comfort. A criteria for lowering the concentration of N₂O was the onset of signs and symptoms characteristic of the excitement state (nausea, agitation).

The need to increase the concentration of N₂O as experience accumulated would suggest that anxiety was not being attenuated and/or insufficient concentrations were being delivered to impact on the patient's situational fear. The implications of the latter are critical to the conduct and findings of this study. Significant group differences could not be expected if inadequate concentrations of N₂O were delivered, or if subjects initially judged to be anxious

were in fact not sufficiently apprehensive. Given the limited sample size, inclusion of non-anxious subjects would have considerable impact on the findings.

An additional concern relates to the possibility that some subjects were too apprehensive to benefit from N₂O, i.e. the potential of N₂O to reduce fear is limited to more moderate or mild anxiety levels. In such cases, increasing N₂O concentration would not serve to facilitate improvements in behavior. The display of high levels of anxiety and uncooperative behavior from a small percentage of subjects in each of the three groups as shown in Figures 5c, 5d, 6c, and 6d support this contention.

Another confounding issue which minimizes the usefulness of assessing the effect of variations in N₂O used relates to the openness of the mask delivery system. Dilution of N₂O with ambient air by virtue of the limited seal around the mask and the inability to control or prevent mouthbreathing pose almost insurmountable problems. The onset of crying and the concomitant nasal congestion also contribute to higher machine flow rates than pulmonary-alveolar uptake. Placement of rubber dam may be expected to reduce the incidence and extent of mouthbreathing. Also, if N₂O proved an effective management tool, then the frequency of -crying behavior/nasal congestion should be minimal.

4. Assessment of the Double-Blindness of the Research Design

Determination of whether the operator could remain blind to the identity of inhalant conditions across treatment experiences was an important and complex issue in the design of this study.

From an observational perspective, if N₂O produced relaxation and facilitated cooperation apart from control conditions, then the operator should have been apt to correctly discriminate between inhalants used. As such, the 72.7% frequency with which correct and independent predictions were made over the 72 mask visits suggests a positive drug effect took place. However, if N₂O was as effective as believed by the majority of clinicians, a higher percentage of correct predictions might have been expected.

Within-subject analysis across all three mask condition visits, (Table 6) found operator prediction to be correct 54.2%. Therefore, on 45.8% the operator was either partially or completely incorrect in predicting group identity on the basis of behavioral responses. This finding suggests that operator blindness was maintained across visits. Also suggested is that the clinician did not perceive differences between the O₂ (placebo) and N₂O condition less than half the time.

An issue unresolved by the data is the impact of possible operator bias on subsequent patient management and response expectations after having made predictions for previous visits. As described in the Dental Visit Protocol section, the operator attempted to maintain a consistent orientation toward patient management responding to specific child behaviors in a standard manner.

Table 6 Operator Predictions of Inhalant Conditions

For Individual Visits (n=72)

	Correct	Incorrect
O ₂	28(71.8%)	11(28.2%)
N ₂ O-O ₂	24(72.7%)	9(27.2%)
Total	52(72.2%)	20(37.8%)

Within Subjects Across Visits 2, 3 and 4 (n=24)

	Correct	Incorrect	Partial
O ₂	7(29.2%)	1(4.2%)	9
N ₂ O-O ₂	6(25%)	1(4.2%)	
Total	13(54.2%)	2(8.3%)	9(37.5%)

Inclusion of the O₂ group was expected to provide data to evaluate the possible placebo effect of the nasal mask itself. Several explanations can be offered to account for why some subjects might derive positive benefits while others display increasingly negative reactions to the mask.

For some children the mask was expected to be perceived initially as threatening and would tend to augment anxiety and uncooperative behavior.

Others would accept the mask with reluctance and anticipation that it would help overcome their fear. One instance of severe verbally and physically resistive behavior which included failure to accept wearing the nasal mask was encountered. The patient was

judged unmanageable in the context of the research setting, was dropped from the study, and received treatment using an alternative modality. If N₂O had the predicted calmative effect, N₂O subjects would be aided in their adaptation to stress posed by the mask. Having been told in a soft, confident, and reassuring tone that breathing "happy air" through the mask would promote relaxation, a placebo effect might be expected.

A possible benefit derived from wearing the nasal mask would include the visual obstruction of oncoming noxious stimuli (e.g. local anesthetic syringe and needle, rubber dam clamp, drill). The impact of viewing (or not viewing) these instruments on subsequent behavior is unclear. Some subjects may be expected to respond better by not seeing the "needle."

Frequently, however, subjects fearful of the unknown insist on viewing the needle, clamp, or drill. At this point, the dentist faces a dilemma. Failure to comply with the child's request, or being "caught in the act" of deliberately hiding the syringe from view is likely to cause mistrust and can only serve to communicate a genuine reason for the child to be alarmed. Alternatively, permitting the child to see the threatening instrument can serve to confirm or exaggerate the child's fear of the impending event. From the child's perspective, justification for ensuing escape and non-coping behavior is ample under both circumstances.

The response of the child to the mask was largely dependent on the manner in which the subject perceived the need or desirability of viewing oncoming stimuli. The data supported a trend toward more uncooperative behavior in O₂ subjects compared to subjects in Groups I and III.

A consistent effort was made to approach this problem in the following manner. The administration of local anesthesia was performed using a "tell-do" approach. Reasonable effort was made to conceal syringes from view. If seen, efforts were made to carry out the task in a positive manner. When visual sighting followed by requests to view the syringe occurred, the syringe was displayed with the needle covered if possible. If the child wanted to view the needle, the operator responded by saying he preferred the child did not. Studies have not been done to determine the impact of various approaches, such as this one on anxious children's responses. It was felt that, the longer the delay in accomplishing the technique, the more exaggerated the resistance and negative behavior.

If N_2O reduced the aversive quality of stimuli, reduced excessive vigilance, and facilitated a realistic appraisal of the limit of threat imposed by the injection or the drilling, differences between groups could be expected. Although statistically not found for HR, the data did indicate strong trends that more cooperative behavior and less arousal resulted from N_2O exposure.

5. Limitations of the Research and Implications for Future Study

It should not be surprising for a study of this nature to encounter numerous problems and difficult to control variables. It was apparent from the literature review why most techniques currently advocated for the management of childhood dental anxiety do not demonstrate an adequate base of empirical support of their effectiveness.

Several obstacles and limitations to the measurement of anxiety and discrimination of a N₂O drug effect on the modification of dental fear and development of coping skills are described below. Despite the many shortcomings, the need to subject proposed anxiety management strategies to a research design which examines the anxiety process prospectively and longitudinally is evident.

An adequate number of anxious subjects with extensive dental disease was required for the completion of this study. To control for expected wide within and between subject variability particularly across physiologic parameters, a larger sample population than used is needed and future investigations must take this into account.

Thirty-eight subjects fulfilled the rigorous selection criteria from among 1,050 children screened over the course of 24 months. Of the 38 invited to participate, 35 completed the series of 6 visits. The limited sample size represents a major pitfall.

The age range chosen was expected to minimize the problem of obtaining an adequate sample of children without prior dental experience who had sufficient restorative treatment needs. A substantial percentage of children in this age range was also expected to manifest marked dental anxiety. The screening selection criteria intended to exclude subjects likely to behave positively in their initial exposure to dental treatment. Surprising difficulty was encountered in satisfying both the anxiety and dental disease criteria. Frequently patients with sufficient disease failed to manifest sufficient anxiety. Similarly, many anxious children failed to have sufficient caries. Inclusion of an additional control group (Group II-O₂) further limited group size.

Retrospective assessment of the sequential physiologic and behavioral responses of individual subjects across visits 1 and 2 indicates that the screening procedures may not have been sufficiently sensitive. For example, despite parental questionnaire and behavioral screening scores suggestive of moderate to high anxiety, a few subjects displayed marked improvement and adaptation to dental stress during visits 1 and 2. Unlike their counterparts, their initially anxious and uncooperative behavior appeared to have been modified quickly by standard verbal communication before the introduction of the inhalant conditions. Subjects 10, 14, 15, and 30 (Group II), and #1 and 29 (Group III) appeared to not have been as anxious as other subjects (See Figures: 9c, d, e, and f.) Given the small group sizes, inclusion of even a few non-anxious subjects may have compromised the opportunity to detect group differences, particularly if subtle in nature.

By the same token, the inclusion of severely anxious and uncooperative subjects who prove refractory to an agent capable only of attenuating more moderate anxiety would likewise reduce the likelihood of detecting differences. The success with which the screening procedures identify subjects who will demonstrate adequate but not excessive anxiety becomes especially critical when sample sizes are small as in this study. Table 5 lists the scores obtained for all subjects within each group on the Behavior Screening and Parental Questionnaire. Examples of each of the above pitfalls are noted. Figure 10 plots the relatively wide distribution of the combination of these scores for each group. Clearly, a larger sample population would be of value in circumventing the difficulties encountered with wide between subject variability.

To minimize the problem caused by either extreme, one or both of the following adjustments in selection criteria may be warranted: (1) inclusion of dentally experienced patients with documentable uncooperative behavior and poor history of coping, (2) delay imposing inhalant conditions until the second restorative visit. Only subjects displaying adequate but not excessive anxiety/uncooperative behavior without N₂O would qualify for assignment to one of the experimental conditions.

An argument could be made for future study to exclude an O₂ (or ambient air) mask control group. Results indicated these subjects display the most arousal and non-coping behavior. A failure to demonstrate a placebo effect, as well as the fact that delivery of O₂ alone is never applied to reduce fear in a clinical context, may be justification for eliminating this group from future studies. Certainly, its elimination would make available additional subjects to increase sample size in the no mask and N₂O groups. Conversely, maintenance of double-blind conditions serves to strengthen the research design by reducing bias due to rater and/or operator expectations. Use of the O₂ group enhances the ability to parcel out a drug effect.

Some concern relates to the value of the self-report measures. The rationale for use of these techniques was described previously. Ultimately, the usefulness and validity of the data obtained from these tests is contingent upon the child's actual comprehension of the task imposed. Given the age tested, variability in socialization and attention span, it is not altogether clear whether the child's

responses were germane to the question which asked them to pick the child he/she felt most like. The certainty with which selections were made either randomly or on the basis of accurate interpretations of the portrayed caricatures is not known. Similarly, with respect to the human figure drawing, factors other than anxiety, (e.g. interest, attention span, and previous drawing experience) may serve as strong determinants of how drawings intended to represent self-portraits were not readily identifiable. Scores obtained on the HFD suggestive of high anxiety were inconsistent with subsequent behavioral and physiologic responses. As such N₂O subjects were found to have higher (more anxious) HFD scores than control subjects across visits. This disparity warrants further assessment as to the validity of this measure as an index of underlying anxiety in the context of this experiment.

Similar concern exists relative to the sensitivity of the clinical rating scales selected for use in the study. As described earlier, few attempts have been made to objectively observe and quantify child behavior in the dental setting. Need remains to develop an instrument sensitive to reflect the range, frequency, and intensity of anxious behaviors seen in children. The observational ratings used in this study provide a qualitative behavioral summary score during specific dental treatment procedures. As structured, these scales did not quantify behavioral response patterns, their frequency or duration. However, judgments of the raters did attempt to take into account the incidence, severity, and duration of behaviors and signs of anxiety in reaching composite scores for a given interval.

Several issues in need of clarification pertain to the measurement and interpretation of physiologic arousal.

The physiological measurement of anxiety is complicated by the experimental conditions since there may be direct pharmacological action of nitrous oxide on certain physiological endpoints. A reduction of physiological arousal in the nitrous condition therefore may reflect either a direct drug action or an indirect effect mediated by relaxation and anxiety reduction.

The literature review did not uncover empirical data documenting direct drug effects on heart rate under the concentrations used. Nonetheless, interpretation of the physiologic findings must be tempered by a recognition of possible pharmacologic actions. Efforts to resolve this issue could be made by examining the time course of physiologic changes and discrete behavioral responses.

Since all dependent measures were not continuous, opportunity for such comparisons were restricted. As such, only global comparisons between heart rate and behavior/anxiety ratings during the injection and cavity preparation were possible. Inasmuch as the clinical ratings provided a summary score for these intervals, the frequency and duration of discrete behaviors were not recorded to permit meaningful time course comparisons.

Where reductions in physiologic arousal were seen under nitrous oxide in the absence of analagous changes in behavioral indices, the interpretation of a direct pharmacological action would seem parsimonious. However, where compatible changes across behavioral and physiologic dimensions were seen and such changes persisted after N₂O discontinuation, then interpretations which implicate the child's

anxiety seem unwarranted. In the latter case, manifestations of physiologic arousal can more readily be attributed to the dental procedures and assumed to reflect the young child's response to dental stress.

The interpretability of physiologic data obtained from adults and particularly children remains controversial. Although, recorded with relative ease, heart rate data frequently displays wide intra- and inter-individual variability. It is, therefore, not surprising that the magnitude of the response differential between experimental conditions must be large to detect statistically significant group differences. Further, what standard deviation in heart rate constitutes a clinically significant difference is neither clear nor easily defined.

While believed more sensitive indicators of situational anxiety, peripheral measures such as skin conductance and EMG are especially difficult to record in the child patient. As described in the literature review and data collection protocol, arduous techniques to interpret this data have been developed. However, the validity of this data requires recording circumstances in which movement artifact can be discounted.

Control of limb movement (to maintain surface-electrode contact) to enable accurate interpretation of skin conductance data was not possible in this study.

Need remains to explore other less labile measures more immune to the perpetual motion of children. Use of respiratory rate and depth of respiration may be one such measure. It seems likely that episodes of acute situational anxiety may be accompanied by

alterations in these parameters. Such findings could be expected to contribute greatly to our anxiety measurement approaches. The technology is currently available to permit recording these two parameters. One simple technique would include the use of a simple pressure transducer placed around the child's chest. A more effective and less obtrusive technique would be to record rate and depth of respiration through the same three surface precordial electrodes through which heart rate is recorded. This can be accomplished simultaneously with heart rate via a multi-channel polygraph equipped with the appropriate biotachometer, pneumograph, and universal coupler components.

Given the variation in activation and response patterns within and between subjects, use of multiple physiologic parameters seems warranted. The inclusion of self-reports, parental assessments, observation ratings along with multiple non-invasive physiologic measures may have its chief utility, despite individual drawbacks, in cross-validating each other and ensuring that important dimensions are not missed.

The opportunity to detect group differences is dependent largely upon the specific intervals during which data sampling occurred. Inclusion of extraneous time blocks not representative of stress-provoking procedures serves only to dilute the events in which assessment of situational stress or its mediation is critical.

The absence of group differences would therefore not be surprising where analyses evaluate visits inclusive of all baselines and event intervals. Greater resolution of the data achieved by excluding baseline periods would increase the likelihood of detecting

group differences attributable to drug effects. Dissection of a visit to examine specific single events further enhance the ability to test the hypotheses. However, point at which subdivision of a given interval into further segments to permit valid conclusions to be reached is not clear.

In the present study mean values were derived for each one minute data interval. Maximum and minimum values were obtained during each 15 seconds of the 1 minute period, but not evaluated due to an inability to code the frequency, intensity, and timing of specific behaviors. It was not possible to determine which 15 second interval was the most painful or stressful; extreme variability occurred within and between subjects as well as across intervals and visits. As result, analysis was limited to looking at mean differences across each full 1 minute interval.

Other potential pitfalls of the research focus on the N₂O delivery protocol. The implications of delivering either inadequate or excessive N₂O flow rates have been described. The likelihood of delivering excessive concentrations seems remote in view of the absence of nausea/vomiting, common side effects associated with the excitement stage. The possibility that sub-therapeutic levels of N₂O could have been delivered is not as easily discounted, however. In the presence of group differences, the assumption that this did not occur seems appropriate. However, in the absence of group differences, this possibility cannot be ruled out.

To insure adequate N₂O gas flow, future studies might best adopt a delivery protocol which initiates flow at 40-45% with titration occurring only in a downward direction contingent to the onset and recognition of signs of the excitement stage. Although this may

preclude the delivery of inadequate N₂O flow rates, the incidence of nausea/vomiting could be expected to increase. If so, the negative consequences of this adverse side effect may impede subsequent patient acceptance of the nasal mask. This latter concern, however, should be minimal in view of substantial data which reports an extremely low incidence of nausea at 45% N₂O. Safeguards which include minimal food consumption during the meal prior to the visit should permit 40-45% N₂O flows to be used. This approach seems warranted to circumvent the possibility of delivering inadequate N₂O concentrations.

Variables not addressed by the research study were the impact of dentist behavior, and his/her relative ability to derive maximum benefit from the experimental technique. Although efforts were made to maintain a consistent approach to behavior management, no assessment of dentist behavior was made. Research subsequent to the data collection has suggested that a given management approach may be in general more or less effective; efforts to select out the effectiveness of the technique should include assessment of the impact of variation in which dentists apply these approaches. A research design involving multiple operators would therefore be useful in this regard; however, addition of this dimension would demand a corresponding increase in sample size.

Another parameter, not included in this study, but one easily incorporated, involves an evaluation of the quality of care performed under different experimental conditions. If N₂O produced a more cooperative subject, it could be expected that compared to control subjects, a higher quality of care could be provided for subjects

receiving N₂O. Demonstration of this finding would be of obvious practical significance to the clinician. Testing of this hypothesis would seem appropriate for this project as well as one involving multiple operators.

A final concern relates to the applicability of the research findings to the clinical context. Arguments could be raised that the findings have limited generalizability to pedodontic practice since the procedures and environment differ markedly from those in the typical dental office. Particular concerns center around a possible obtrusive, threatening, or anxiety-provoking effect of the data collection procedures.

As discussed earlier, impressions on conducting the longitudinal project do not support these concerns. Our subjects typically adjust readily to the physiological recording and behavioral observation procedures. It has not been uncommon for a child to forget the electrodes and, at the completion of the visit, attempt to leave the dental chair with wires still attached. Children seem to look forward to the playful atmosphere created by our procedures. Observations of the ready acceptance of the research routines suggest that the experimental procedures do not systematically modify children's responses from those seen in the private or clinic-dental setting. However, need exists for objective data bearing on this question of generalizability.

Only by way of comparative study of children's responses in both the research setting and several typical pedodontic office settings can this issue be addressed. It would be hypothesized that any

difference between the dental research setting and the private settings would be no greater than the differences among the private practices themselves.

F. CONCLUSIONS

1. From a statistical point of view only subjective measures of anxiety and cooperative behavior identified significant group differences to substantiate the claim that N₂O facilitates behavior management of the anxious young pedodontic patient.

2. Due to the limited sample population size and wide intra-individual variability, further clarification of group differences across physiological parameters (mean HR) was not possible. From a practical standpoint, all indications suggest that N₂O did serve to reduce arousal during the most stressful procedures of a dental visit.

3. It appears that N₂O is of benefit relative to the development of coping skills and attitude toward acceptance of treatment at subsequent visits. Further longitudinal research which utilizes larger sample populations and more visits is needed to clarify this interaction.

G. SUMMARY

N₂O has acquired widespread use as a tool for managing young dentally anxious children. Clinical impressions have suggested that

N₂O eliminates the child's uncooperative behavior while also alleviating anxiety and facilitating the emergence of coping skills. With the exception of the present study, empirical data to support these claims documenting the effects of N₂O across sequential visits or the impact of discontinuing its use have not been presented.

The present study was designed to provide data to address these issues. An experimental demonstration of N₂O's effectiveness should encourage its application to those patients whom it might benefit. Data regarding nitrous' effect across sequential visits and the impact would potentially guide its most effective use, prevent the possible development of patient dependence and reduce occupational exposure of N₂O to dental personnel.

Utilizing a longitudinal approach under double-blind conditions, children receiving N₂O were compared with children in two control groups using a combination of self-report, behavioral, and physiological measures.

In concentrations ranging from 20-50%, N₂O appeared to reduce uncooperative and anxious child behavior during the more stressful procedures of a restorative dental visit. Compared to control subjects, children with a history of N₂O exposure demonstrated and sustained more favorable responses to injections and cavity preparations during and following the discontinuation of the inhalant.

Although not statistically shown to have reduced mean heart rate, all trends indicated that N₂O did serve to reduce arousal during the more anxiety-provoking procedures from a practical standpoint.

On the basis of the limited sample studied in this project, it appears that N₂O was not an effective management tool to overcome severe of anxiety and uncooperative behavior.

Research which attempts to clarify the impact of a particular intervention on anxiety reduction, the development of coping skills, or the modification of patient attitudes toward care can anticipate encountering numerous and complex methodological obstacles. Nevertheless, it seems important that longitudinal approaches are necessary to provide data relative to the short and long term consequences of proposed anxiety management strategies. Further work seems particularly urgent to develop improved methods by which problems associated with inadequate sample sizes, patient selection criteria, the measurement of childhood dental anxiety, operator variability, openness of the nasal mask delivery system and mouthbreathing can be resolved.

Further study of the effects of N₂O in anxious young patients utilizing a larger subject population seems warranted to further clarify these interactions.

Additionally, some clinicians have advocated the use of N₂O as an adjunct to managing the behavior of neurologically handicapped dental patients. To date, no study has reported N₂O's effects or effectiveness in this population. The availability of normative data would prove helpful in the design of subsequent studies involving subjects limited in cooperative ability.

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APPENDIX I-A

PARENTAL QUESTIONNAIRE FOR SCREENING VISIT

The information below will help the dentist to understand and treat your child. Please answer all questions as carefully and honestly as you can. Thank you.

Has your child ever had a painful or upsetting facial injury?

_____ Several times.

_____ Once or twice.

_____ Never.

How does your child react to visiting the medical doctor? (Check one in each column.)

_____ Usually likes

_____ Not at all nervous.

_____ So-so.

_____ A little nervous.

_____ Usually dislikes

_____ Very nervous.

Has your child had visits to the medical doctor which he/she found very painful or upsetting?

_____ Several times.

_____ Once or twice.

_____ Never.

How does your child react to injections?

_____ Not at all nervous or upset about getting a shot.

_____ A little nervous or upset about getting a shot.

_____ Very nervous or upset about getting a shot.

What have you told your child about this dental visit?

_____ I told him/her a great deal about what dentists do.

_____ I told him/her a little about what dentists do.

_____ I told him/her nothing about what dentists do.

Does your child think anything is wrong with his/her teeth or mouth (cavity, chipped tooth, canker sore, etc.)?

_____ My child definitely thinks something is wrong.

_____ My child is a little worried about his/her teeth.

_____ My child is not worried at all about his/her teeth.

How do you react to visiting the dentist?

_____ Not nervous at all.

_____ A little nervous.

_____ Very nervous.

How do you feel about bringing your child for his/her first dental visit?

_____ Not nervous at all.

_____ A little nervous.

_____ Very nervous.

Has anyone close to your child had a painful or upsetting dental problem or dental visit in the last couple of years?

_____ Several of my child's family or friends.

_____ One or two of my child's family or friends.

_____ None of my child's family or friends.

How do you think your child feels about his/her first dental visit?

_____ Not nervous at all.

_____ A little nervous.

_____ Very nervous.

APPENDIX I-B

Behavioral Screening Instrument

	Absent	Mild or Brief	Severe or Persistent
Child resists entry to examination room			
Child resists getting into operatory chair			
Child assumes inaccessible position in operatory chair			
Child demands physical contact with or proximity of mother			
Child cries or expresses negative affect			
Child actively or physically resists examination			

APPENDIX II

NITROUS OXIDE, OXYGEN EQUIPMENT

Systems: A Fraser-Sweatman 4-Yoke MDM Quantiflex Machine was used to deliver the inhalants.

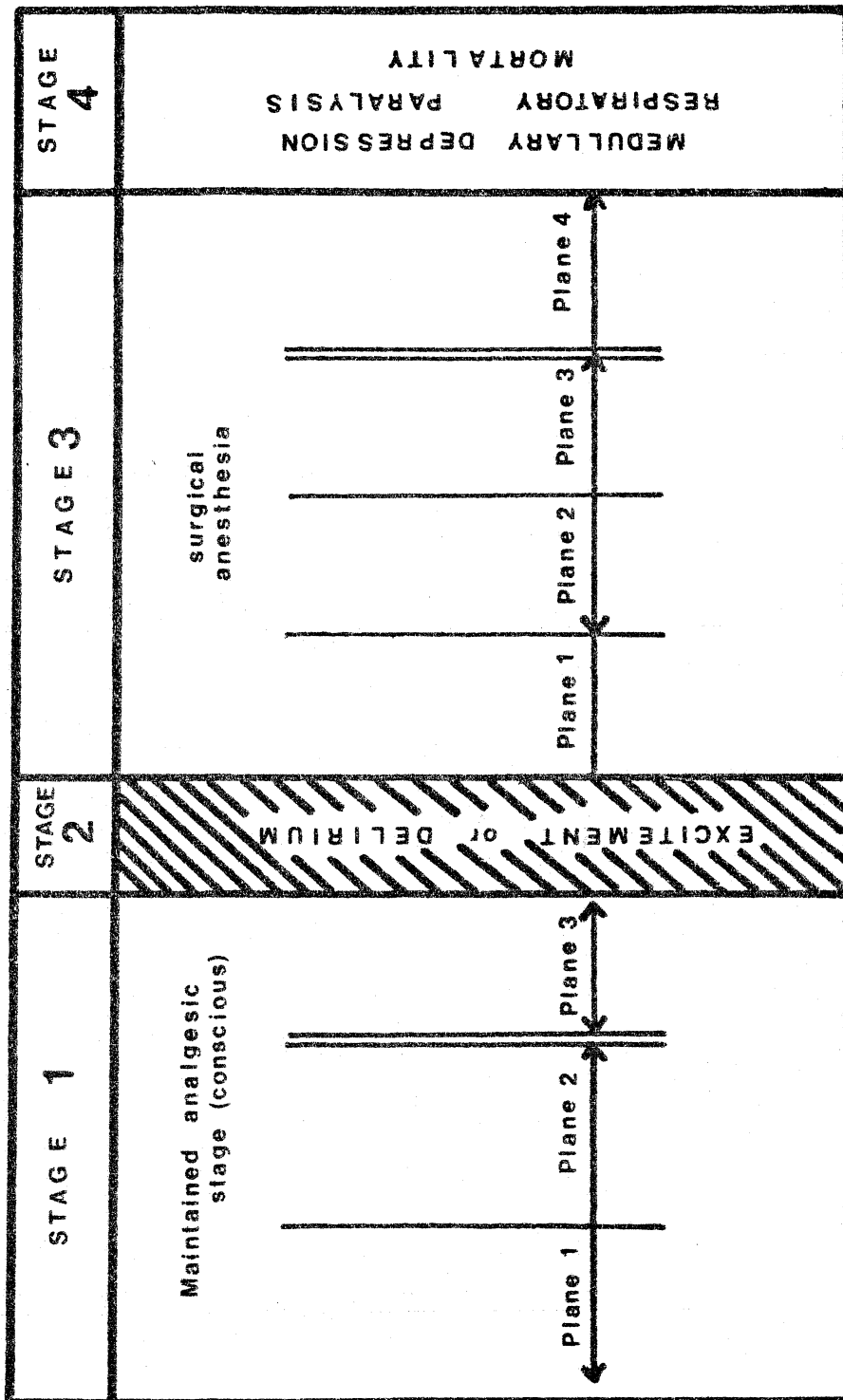
This unit is described below.

Components:

1. Cylinders - Style E steel cylinders with 3/8" thick walls; identified by color-coding (O_2 = green, N_2O = blue) adopted by the medical gas industry, American Society of Anesthetists and American Hospital Association, published by the U.S. Dept. of Commerce. Cylinders bear the dates of commissioning, testing service, pressure, and insignia of testing laboratory. It is recommended that before attaching a cylinder to a machine, careful opening (cracking) be done to remove any small particles of dust obstructing the outlet valve. Storage of cylinders should be away from any heat source.
 - a. N_2O Cylinders: Liquified compressed gas and vapor in equilibrium; pressure is determined by the vapor pressure of the liquid which will remain constant until 7/8 of the liquid is exhausted.
 - b. O_2 Cylinders: O_2 is in a gaseous state. Full cylinders have pressure ranging from 2,000 - 2,500 lb./in.². E Tanks contain 165 gallons with the contents being determined directly from the pressure.

2. Yokes - Hold cylinder in tight contact with the machine intakes.
3. Control Valves - Allow gas to pass directly into the machine by fine control.
4. Regulator - Permits: a) constant flow regardless of cylinder pressures; b) fine control adjustment of flow; c) use of constant, relatively low pressures throughout system.
5. Flowmeter - Indicates the flow rate of the gas being delivered.
6. Reservoir Bag - Insures the patient will always have a plentiful supply which he can draw.
7. Fail-Safe Mechanisms
 - a. These machines are equipped with an auxillary attachment that precludes the possibility of administering N_2O without O_2 . When O_2 flow pressure falls below 15 lbs., flow of N_2O ceases.
 - b. The minimum O_2 flow is 3 liters/minute.
 - c. A resuscitation unit for delivery of positive pressure O_2 is attached.
 - d. A Pin-Index Safety system prevents erroneous interchange of cylinders. Flush-type valves are built around the matching of pins and holes; for each gas there is only one workable combination. Thus, it is impossible for a cylinder of one gas to be inadvertantly attached to a yoke pin-indexed for any other gas.

APPENDIX IIIa



The Stages and Planes of Analgesia and Anesthesia

APPENDIX III-B

SIGNS OF ANALGESIA VERSUS LIGHT ANESTHESIA

	Relative Analgesia	Light Anesthesia
Respiration	Normal, smooth Inspiration of normal duration No phonation No holding of breath or grunting	Superficial slow breathing, often irregular Prolonged inspiration Phonation due to reflexes of pain Holding of breath, grunting
General muscles	No movements, muscles relaxed Facial expression of a conscious individual Nausea extremely rare Purposeful but delayed resistance as result of trauma	Purposeful movement or rigid muscles Facial expression of pain or semi-consciousness. Nausea more frequent Reflex or purposeful resistance as result of trauma
Eye	Pupils normal, contract normally to light Conjunctiva sensitive No rolling of eyeballs Eyelids do not resist opening, wink when touched	Pupils large, contract to light actively Conjunctiva sensitive, Eyeballs roll quite rapidly Eyelids resist opening, wink when touched
Pulse Rate	Normal	Accelerated
Blood pressure	Normal	Normal
Color of skin	Normal	Pink or no change normally In anemics, no color change In plethorics, slight cyanosis

APPENDIX IV
VENHAM'S CLINICAL RATINGS OF ANXIETY AND COOPERATIVE BEHAVIOR

Anxiety Scale

0. Relaxed, smiling, willing and able to converse.
1. Uneasy, concerned. During stressful procedure may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression, may have tears in eyes.
2. Child appears scared. Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, (quiet) crying, hands tense and raised, (not interfering much - may touch dentist's hand or instrument, but not pull at it). Child interprets situation with reasonable accuracy and continues to work to cope with his/her anxiety.
3. Shows reluctance to enter situation, difficulty in correctly assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance.
4. Anxiety interferes with ability to assess situation. General crying not related to treatment. More prominent body movement. Child can be reached through verbal communication, and eventually with reluctance and great effort he/she begins the work of coping with the threat.
5. Child out of contact with the reality of the threat. General loud crying, unable to listen to verbal communication, makes no effort to cope with threat. Actively involved in escape behavior. Physical restraint required.

Cooperative Behavior Scale

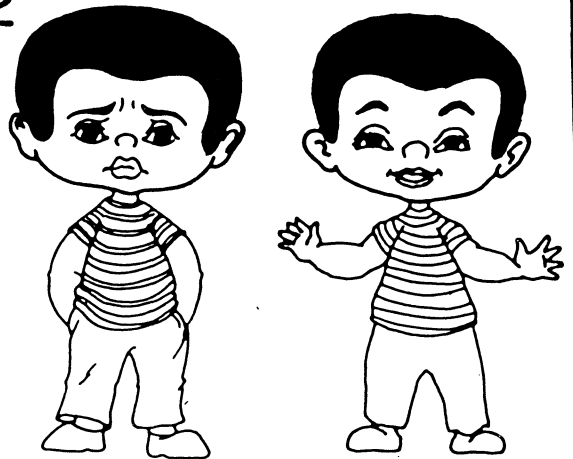
0. Total cooperation, best possible working conditions, no crying or physical protest.
1. Mild, soft verbal protest or (quiet) crying as a signal of discomfort, but does not obstruct process. Appropriate behavior for procedure, i.e., slight start at injection, "ow" during drilling if hurting, etc.
2. Protest more prominent. Both crying and hand signals. May move head around making it hard to administer treatment. Protest more distracting and troublesome. However, child still complies with request to cooperate.
3. Protest presents real problem to dentist. Complies with demands reluctantly, requiring extra effort by dentist. Body movement.
4. Protest disrupts procedure, requires that all of the dentist's attention be directed toward the child's behavior. Compliance eventually achieved after considerable effort by dentist, but without much actual physical restraint. (May require holding child's hands or the like to start.) More prominent body movement.
5. General protest, no compliance or cooperation. Physical restraint is required.

APPENDIX V-A
Picture Selection Task

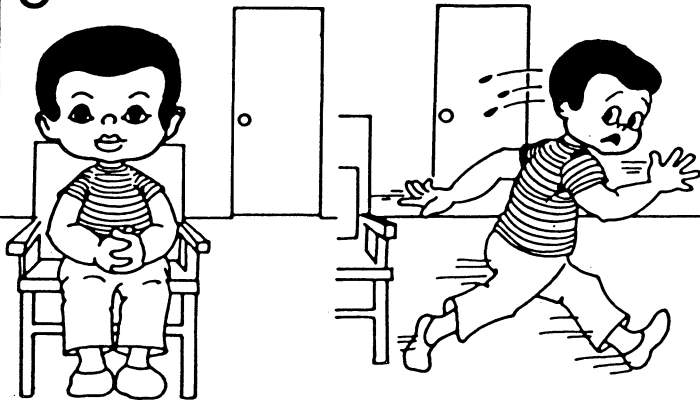
1



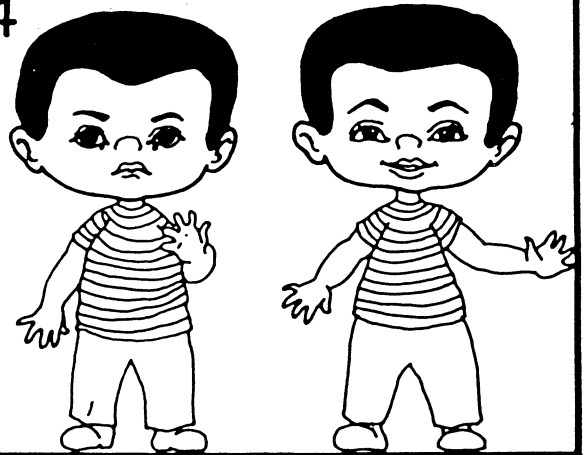
2



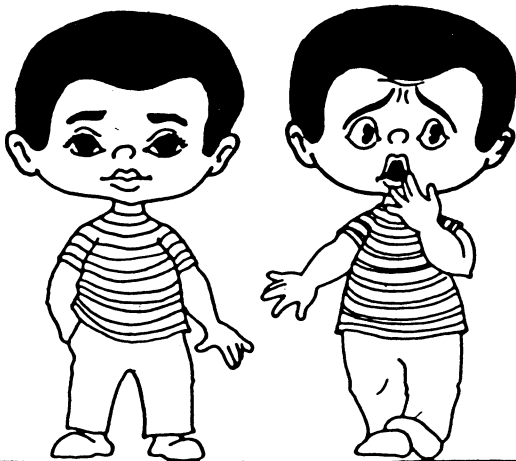
3



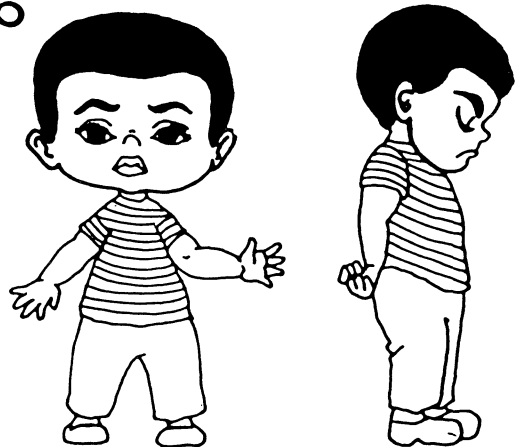
4



5



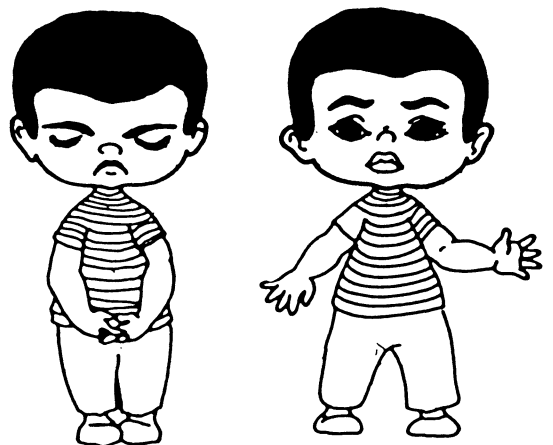
6



7



8



APPENDIX V-B

SCORING SYSTEM FOR HUMAN FIGURE DRAWING

1. Omission of Arms - Score 0 if arms and hands are present. Score 3 if partially present. Score 6 if absent.
2. Smile - Presence of a smile requires an upward curve of the main line of the mouth. If the mouth consists of only 2 lines, the bottom line must be curved up and the top line must be straight or curved up also. Score 0 if smile is present. Score 2 if absent. Score 4 if the mouth is not drawn.
3. Figure Size - Measure size of figure drawing to nearest 1/4 inch. Include hat and high heels. Do not estimate incomplete figure. Score is 4.5 minus actual size of figure with minimum score of 0.
4. Head to Body Ratio - Score 0 if height of head is less than 1/5 height of whole figure or more than 1/8 height of the figure. Score 2 if height of head is greater than or equal to 1/3 height of the figure. Score 4 if height of head is less than or equal to 1/8 the height of the figure.
5. Humor, Theme or Movement - Humor refers to a drawing of a funny situation such as a lady with a bottle emitting a "hic". Theme refers to addition of objects beyond clothes, hat and body such as an object in the hand. Movement refers to body posture clearly portraying action such as walking, running or throwing a ball. Score 0 if any of the three are present and 2 if none is present.
6. Size - Measure the distance from the bottom to the top of the figure to the nearest 1/4 inch. Score 0 if figure is 4.5 inches, 1 if less than 4.5 inches and 2 if larger than 4.5 inches.

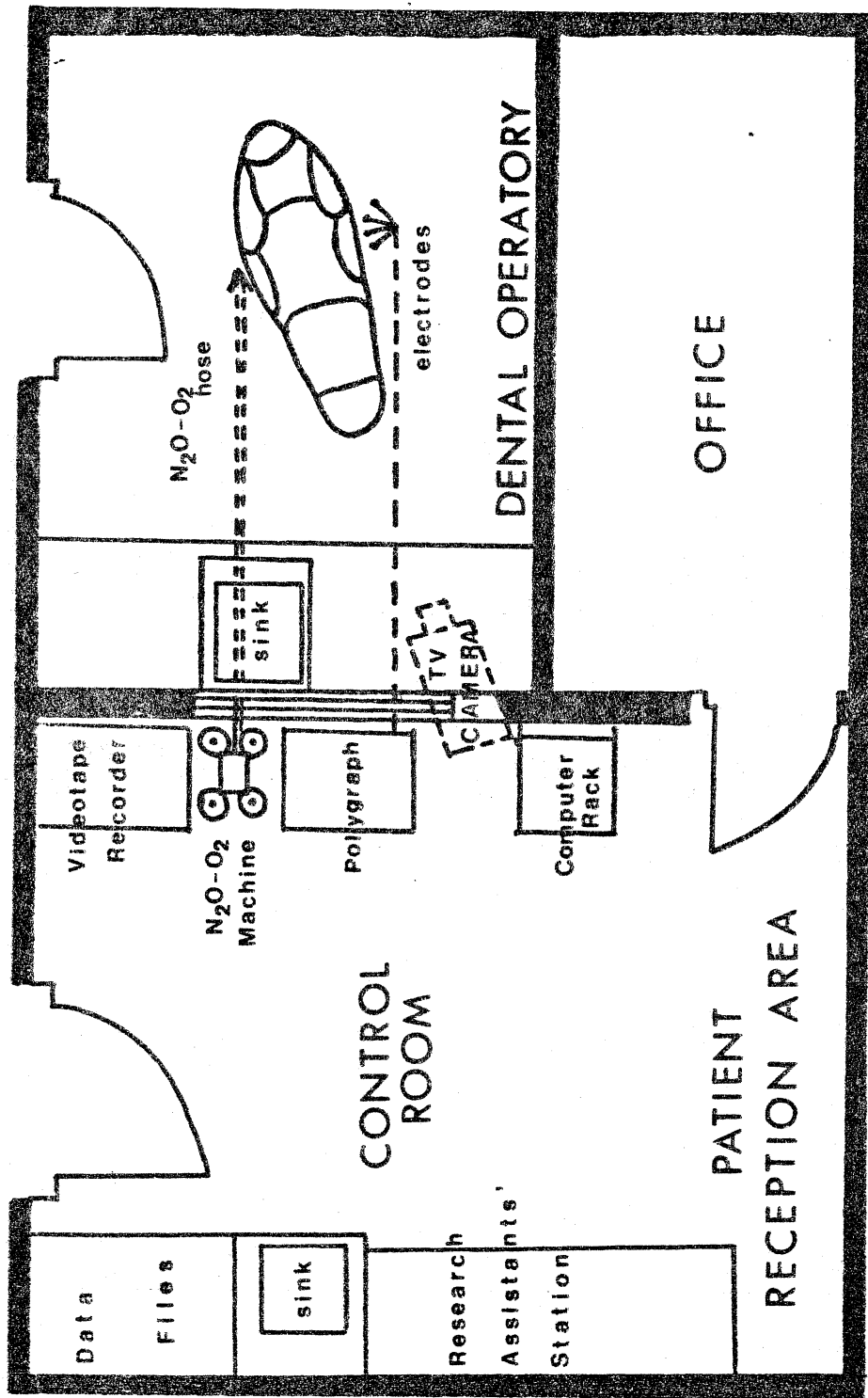
APPENDIX VI

PHYSICAL LAYOUT OF RESEARCH FACILITIES

FLOOR PLAN OF FACILITIES

INSTRUMENTATION

APPENDIX VIa



FLOOR PLAN OF FACILITIES

APPENDIX VI b

